NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

Lay Person Usability Study Report

Final Report Date: 2020-11-20

Table of Contents

Signature of Study Director and Verification Dates

This study meets the technical requirements of the protocol, also meets the technical specifications for the test.

Study Director: 5.1.2e

Company: Atlas Link Technology Co., Ltd

Position: 5.1.2e

Signature: 5.1.2e

Verification Date: 2020-11-20

Study Summary

A consumer use study was conducted to determine NOVA Test® SARS-CoV-2 Antigen Rapid Test (Colloidal Gold Immunochromatography) performance when used by unassisted lay users following the Instructions for Use. The study was conducted in two ways: 1) Performance of the consumer at home with self-collected sample; 2) Performance of the consumer with provided sample.

All 175 consumer cases including 102 self-testing consumers at home with self-collect sample and 73 consumers with provided samples were analyzed. Data from self-testing showed that all of them carried out the test correctly and 100% of the results were consistent with that of laboratory. Questionnaires from both groups showed over 99% of them also thought the testing is easy to perform. In conclusion, NOVA Test® SARS-CoV-2 Antigen Rapid Test is suitable for self-testing.

1. Purpose

To evaluate NOVA Test®SARS-CoV-2 Antigen Rapid Test suitability as self-testing device: Lay Person self-testing was performed, and the results were compared with that from professional test.

2. Reference and Compliance

FDA Guidance for In Vitro Diagnostic Medical Device

NMPA Guidance

The study was conducted based on SARS-CoV-2 Antigen Rapid Test Quality Control Standard

This study conforms to all applicable laws and regulations.

3. General description

3.1 Test design

A consumer use study was conducted to determine NOVA Test® SARS-CoV-2 Antigen Rapid Test performance when used by unassisted lay users following the Instruction for Use. The study was conducted in two ways: 1) Performance of the consumer at home with self-collected sample; 2) Performance of the consumer with provided samples.

In the study of the consumer at home with self-collected sample, 102 participants were chosen for self-tested. The self-collected specimens were stored in an approximate method and sent to laboratory for professional check. At the same time, a questionnaire and corresponding analysis were carried.

In the study of the consumer with provided samples, 73 persons were chosen to evaluate NOVA Test®SARS-CoV-2 Antigen Rapid Test with provided samples. The provided samples included four SARS-CoV-2 virus culture levels: 1000 $TCID_{50}$/ml, 200 $TCID_{50}$/ml, 50 $TCID_{50}$/ml, 10 $TCID_{50}$/ml. At the same time, a questionnaire and corresponding analysis were carried.

3.2 Questionnaire compilation

To record the test and evaluate the test, a questionnaire was drafted. It mainly concentrated on personal check, user test procedure. The objective of the evaluation was clearly indicated in the questionnaire, it was mainly made up of four parts:

(1) Personal information: It is mainly to get a detailed record of the consumer. Other information could also be included if the consumer thinks it responsible for the test. The detective results were indicated in the questionnaire.

(2) Strip information: It is partially to carry out health condition by the user and to evaluate its quality partially.

(3) Test procedure: This is to investigate if the Instruction for Use can direct lay persons to perform the test correctly. That is to investigate if the Instruction for Use is suitable.

(4) The actual performance characteristics:

According to the characteristics of IVDs, the possible results includes: ① Correct results; ② False negative; ③ False positive; ④ No result. Unexpected results may also occur. For the study of the consumer at home with self-collected sample, the test results were compared with qRT-PCR Test by laboratory professions, and the agreement between the results obtained by home user and those obtained by laboratory professionals reading the same test device were analyzed. Other relevant information is also included in the questionnaire.

4. Performance of the consumer at home with self-collect sample

4.1 Case determination

The 102 cases were randomly chosen from Lang fang city, China, their culture backgrounds involved Deliver, driver, teacher clerk etc. Their educational backgrounds ranged from Elementary school to master or higher. None of them had received any training or other information provided in the Instruction for Use.

4.2 Self-testing and hospital examination

Each of them was dispatched SARS-CoV-2 Antigen Rapid Test from three batches: 20200817, 20200818, 20200819. Specimen collection was performed according to the Instruction for Use. One portion was for test device detection and the other portion was left for hospital examination. The test with the test device was performed at the consumer's home. The test procedure was pursued on according to the Instruction for Use. Immediately after the test, the individual was asked to fill out "Lay person Usability Study Form" in the questionnaire.

Clinical Laboratory Department, the Ditan Hospital, Beijing, PRC. carried out the hospital examination. The hospital resume should be well-preserved to track the results. The whole

questionnaire was finished by now.

4.3 Questionnaire

After about 6 months, the questionnaires were gathered, we reviewed the questionnaire. The data were analyzed and compared.

4.4 Results from questionnaires

The questionnaires were processed, and the results are shown as follows:

4.4.1 Consumers information

Table 1 Age distribution:

To be clearer about the results, their age ranges were divided into five parts.

Age Group	18~30	31~50	51~70	Over 70
Number	26	42	15	19

Table 2 Culture Background

Profession	Police	Deliver	Teacher	Driver	Clerk	Others
Number	7	19	12	34	23	7

Table 3 Educational background

Education	Elementary school	High School	Bachelor	Master or higher	Others
Number	2	35	52	9	4

The consumers' ages range from 18 to 75, and most of them were from 31 to 50. They have also showed different culture background: most of them were those whose occupations has higher risk of exposure and infection. The list also reflected their educational difference, most of them (100/102) were over high school graduates and only two elementary school graduated, there were 52 bachelor and 9 master or higher respectively.

4.4.2 Test Device information

Of the test device dispatched for test, none of them was damaged or wet when they were firstly opened, and all the necessary components are present. No non-conformity of label with Instruction for Use was found. Each of them was within its shelf-life. In conclusion, no quality problems were found based on the physical examination. All of them were stored at 2 ~ 30 °C before use.

4.5 Test procedures

4.5.1 Collection and storage of specimen

All consumers collected their nasal swab specimens following NOVA Test instruction for Use. All specimen was stored the at room temperature and taken to hospital in 12 hours. All of them carried out the test after balancing specimen to room temperature (15°C to 30°C).

4.5.2 Test procedure

All the consumers tested their self-collected specimen with NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit following the Instruction for Use. They all read the results easily and correctly. All of them understood the test procedure easily and carry out it correctly.

4.6 Test Results and Accuracy

In the study of the consumer at home with self-collected sample, 102 participants in this study obtained 24 positive and 88 negative test results. No invalid was observed. There was 100% (102/102) agreement between the results obtained by the home users and those obtained by laboratory professionals reading the same test device.

NOVA Test®SARS-CoV-2 Antigen Rapid Test results from self-test were compared with a reference kit (SARS-COV-2 R-GENE® - Real Time Detection kit) provided by BioMérieux. According to the Instruction of reference test, CT value ≤ 30 is considered as the criterion for distinguishing between negative and positive judgments.

Table 4 Results from self-test and the reference method by hospitals

	NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit		
BioMérieux	Positive	Negative	Total
Positive	23	3	26
Negative	1	85	86
Total	24	88	102

For the 102 results from self-test, it showed 95.8% positive conformity with that from reference test and that of 96.6 % negative conformity.

4.7 Remarks given by the consumers

The remarks given by the consumers were listed as follows including the clarity of the Instruction for Use, feasibility of the test devices:

Table 5 Remarks on the clarity of the Instruction for Use

Remarks	Very clear	Clear	Ambiguous	Very ambiguous
Instruction for Use	95	7	0	0

Interpretation of results	93	9	0	0

Table 6 Remarks by the consumers on its manipulation

Remarks	Very easy	Easy	Difficult	Very difficult
Quality	87	14	1	0

Over 99 % of them thought the package insert is clear and easy to follow.

4.8. Conclusion

All 102 consumer cases were analyzed. Data analysis showed that all of them carried out the test correctly and 100% of the results were identical with that of laboratory. They also thought the testing is easy to perform. In conclusion, NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit is suitable for self-testing.

5. Performance of the consumer with provided samples

5.1 Case determination

The 73 cases were randomly chosen from Lang fang city, China, their culture backgrounds involved worker, farmer, teacher clerk etc. Their educational backgrounds ranged from Elementary school to master or higher. None of them had received any training or other information provided in the Instruction for Use.

5.2 Consumer with provided samples

Each of them was dispatched SARS-CoV-2 Antigen Rapid Test from three batches: 20200817, 20200818, 20200819. The provided samples included four SARS-CoV-2 virus culture levels: 1000 $TCID_{50}$/ml, 200 $TCID_{50}$/ml, 50 $TCID_{50}$/ml, 10 $TCID_{50}$/ml. Consumers carried out the test procedure with the provided nasal swab samples and the test device and interpreted the test results following the insert. Immediately after the test, the interviewee was asked to fill out "Lay person Usability Study Form" in the questionnaire.

5.3 Questionnaire

After about 5 days, the questionnaires were gathered, we reviewed the questionnaire. The data were analyzed and compared.

5.4 Results from questionnaires

The questionnaires were processed, and the results are shown as follows:

5.4.1 Consumers information

Table 7 Age:

To be clearer about the results, their age ranges were divided into five parts.

Age Group	18~30	31~50	51~70	Over 70
Number	7	38	15	13

Table 8 Gender

Male	34
Female	39

Table 9 Culture background

Profession	Police	Deliver	Teacher	Driver	Clerk	Others
Number	3	15	9	20	21	5

Table 10 Educational background

Education	Elementary school	High School	Bachelor	Master or higher	Others
Number	0	25	36	8	4

The consumers' ages range from 18 to 72, and most of them were from 31 to 50. They have also showed different culture background. Most of them were over high school graduates and there were 36 bachelors and 25 from high school.

5.4.2 Test Device information

Of the test device dispatched for test, none of them was damaged or wet when they were firstly opened, and all the necessary components are present. No non-conformity of label with package insert was found. Each of them was within its shelf-life. In conclusion, no quality problems were found based on the physical examination. All of them were stored at 2 ~ 30 °C before use.

5.5 Test procedures

5.5.1 Storage and distribution of the prepared specimen

The prepared nasal swab samples were stored at 4°C and distributed to consumers accompanied with test device before testing. All of them carried out the test after balancing specimen to room temperature (15°C to 30°C).

5.5.2 Test procedure

All the consumers tested the provided specimen with NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit following the instruction for use. They all read the results easily and correctly. All of them understood the test procedure easily and carry out it correctly.

5.6 Test Results and Accuracy

In the study of consumers test with provided samples, 73 people (34 male and 39 female) participated. All results showed 100% agreement.

Table11 Results from consumer with provided samples

Sample type	Concentration (TCID50/ml)	Negative	Positive	Invalid	Total	%Correct
P1	1000	0	12	0	12	100
P2	200	0	12	0	24	100
P3	50	0	12	0	36	100
N1	10	37	0	0	73	100
	Total	37	36	0	73	100

5.7 Remarks given by the consumers

The remarks given by the consumers were listed as follows including the clarity of the Instruction for Use, feasibility of the test device:

Table 12 Remarks on the clarity of the package insert

Remarks	Very clear	Clear	Ambiguous	Very ambiguous
Instruction for Use	65	8	0	0
Interpretation of results	68	5	0	0

Table 13 Remarks by the consumers on its manipulation

Remarks	Very easy	Easy	Difficult	Very difficult
Quality	59	14	0	0

5.8 Conclusion

All 73 consumer thought the package insert is clear and easy to follow, the results was easy to read.

6. Conclusion

All 175 consumer cases including 102 self-testing consumers at home with self-collected sample and 73 consumers with provided samples were analyzed. Data from self-testing showed that all of them carried out the test correctly and 100% of the results were identical with that of laboratory. Questionnaires from both groups showed over 99% of them also thought the testing is easy to perform. In conclusion, NOVA Test® SARS-CoV-2 Antigen

Rapid Test is suitable for self-testing.

7. Report

1) Original raw data is archived in Quality Control Department.

2) Original final report is archived in Quality Control Department.