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

Usability Engineering Process Report

Final Report Date: 2020-10-18

Study Director Signature and Verification Dates

This study meets with the technical requirements of the protocol. The study also meets with technical specification for the test.

Study Director: 5.1.2e

Company: Atlas Link Technology Co., Ltd

Position: 5.1.2e

Signature: 5.1.2e

Verification Dates:2020-10-18

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1 Application specification

1.1 Intended medical indication

NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is an immunochromatographic membrane assay that uses the double-antibody sandwich method to detect the novel coronavirus (SARS-CoV-2) nucleocapsid protein from Anterior nasal swab specimens from patients who are suspected of COVID-19 by a healthcare provider. Performance of the test is limited to certified laboratories and self-test.

1.2 Intended PATIENT population

Novel coronavirus pneumonia (Coronavirus disease 19, COVID-19) is an infectious disease caused by SARS-CoV-2 infection. On February 11, 2020 the International Committee for Taxonomy of Viruses (ICTV) renamed the virus SARS-CoV-2. Its clinical manifestations contain fever, fatigue, and dry cough. A few patients have nasal congestion, runny nose, and sore throat and diarrhea and other symptoms. In severe cases, dyspnea and / or hypoxemia usually occurs after one week. Some critical patients show distress syndrome, septic shock, metabolic acidosis that is difficult to correct, and rapidly develop coagulopathy.

1.3 Intended part of the body or type of tissue applied to or interacted with

Anterior nasal swab or nasopharyngeal swab (NP Swab) are used for the detection. The assay kit doesn't directly contact in vivo with any part of the bodies. It is an in vitro diagnostic assay kit. The swab specimens are collected based on the instruction for use procedures and the corresponding swab specimens are to be collected in the clinical lab or home.

1.4 Intended USER PROFILE

The intended users are individuals who have not been special trained in testing techniques and professional trained healthcare provider.

1.5 Intended conditions of use

The product is used in self-test and certificated laboratories.

1.6 Operating principle

NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is an immunochromatographic membrane assay that uses the double-antibody sandwich method to detect the novel coronavirus (SARS-CoV-2) nucleocapsid protein from Nasopharyngeal swab (NP Swab) and Anterior nasal swab specimens. SARS-CoV-2 specific antibodies and a control antibody are immobilized onto a membrane support as two distinct lines and combined with other materials to construct a test strip.
If SARS-CoV-2 viral antigen is present, it will migrate on membrane, reach to test area and caught by specific antibody to form a complex result in a visible red ribbon on Test line(T line).
If the quality control line (C line) does not appear, it means that the test result is invalid. This sample needs to be tested again.

2 Frequently used functions

NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is for one single use and its main function is to offer qualitative detection of SARS-CoV-2 Antigen in human nasal swab and nasopharyngeal swab. It is intended for self-test and professional use as an aid in diagnosis of SARS-CoV-2 infection

3 Identification of HAZARDS and HAZARDOUS SITUATIONS related to USABILITY

3.1. Identification of characteristics related to SAFETY

See Risk Management Report

3.2. Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS

See Risk Management Report

4 PRIMARY OPERATING FUNCTIONS

The primary operating functions are shown in the following table:

1. Pull up to remove the cap from the extraction dropper: Place it on a clean surface where you can easily find it.
2. Dispense assay diluent into extraction dropper: Twist off the cap of assay diluent. Dispense(add) all liquid into extraction dropper.
3. Place the dropper on the hole of package box: Softly place the extraction dropper on the hole in front surface of package.
4 Open the cassette aluminum foil bag: Open the foil bag at notch part. Place cassette on a plat surface.
5. Open the package with the swab: Peel open where indicated. Pull swab out of its packaging.
6. Collect sample from nostril: To collect an anterior nasal swap sample, Insert the swab into one nostril just until the soft tip is no longer visible. Rotate it in a circle around the inside edge of your nostril 3 times.
7. Collect sample from another nostril: Use the same soft tip to repeat the previous step in the second nostril 3 times.
8. Put the swab in the collection tube: The soft tip of the swab that went into your nose should go into the tube first. Soak the swab completely in the solution.
9. Rotate and squeeze the swab: rotate and squeeze the soft tip at same time at least 10 times. Then dispose the used swab into biohazard waste bag accord with local legislation.
10. Push cap down firmly and standing: Push the cap straight down onto the dropper. Then place it back to the hole of package and stand for 1 minutes.
11. Dispense the assay diluent into sample well: Squeeze the dropper and dispense(add) 3 drops of assay diluent straightly into cassette sample well.
12. Read result at 15 minutes: Start counting. Read result in 15minutes and interpretate result with instruction.
13. Collect all the package component and sealed in biohazard waste bag: including extraction dropper, swab, test cassette and assay diluent bottle. Discard waste bag accord with local legislation.

5 USABILITY SPECIFICATION

Task	USABILITY goal	Potential USE ERRORS	Design points to consider
TEST PREPARATION 1. Wash hands. 2. Blow nose.	Reduce the impact of mucous substances in the test. Removing unclean hands affects the sample and test cassette, resulting in incorrect test results. USERS should prepare for the performance of test according to the Instruction for Use.	• Blow nose unthoroughly. • Wash hands unthoroughly. • Start the test when the hand is still wet.	• Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.
3. Pull up to remove the cap from the extraction dropper: Place it on a clean surface where you can easily find it.	Open the extraction dropper to allow the liquid to be added.	• USERS don't know which is the cap of extraction dropper. • USERS may lose cap of extraction dropper.	• The lid of the extraction dropper is pre-inserted into the tube or choose an integrated product • Remind in the Instruction for Use.
4. Dispense assay diluent into extraction dropper: Twist off the cap of assay diluent. Dispense(add) all liquid into extraction dropper.	Preload the assay diluent to make it easier to achieve subsequent testing procedures after sampling.	• USERS may spill out assay diluent.	• The top of the diluent bottle is designed into a narrow structure to ensure smooth and steady liquid flow.
5. Place the dropper on the hole of package box: Softly place the extraction dropper on the hole in front surface of package.	Provide a support for the extraction tube to subsequent testing procedures.	• USERS may not find where to put the extraction dropper. • The holes in the package do not allow the tube to be perpendicular to the plane or the tube to spill out easily.	• Obvious instruction and indication show on package and Instruction for Use. • The diameter of the hole is designed to be slightly smaller than the diameter of the tube to secure the tube.
6. Open the cassette aluminum foil bag: Open the foil bag at notch part. Place cassette on a plat surface.	Place cassette to a plane and ready to start a test.	• USERS may don't know how to open an aluminum foil bag. • USERS may place the test card on the bevel and result in incorrect test results	• Notches and indication are designed at the edge of the pouch to ease the opening. • Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.
SPECIMEN COLLECTION Anterior nasal swab 1. Open the package with the swab: Peel open where indicated. Pull swab out of its packaging.	Allow the USERS to obtain the swab without contaminating it. Allow the USERS hold the swab in the correct position.	• USERS may don't know how to open swab package. • USERS may hold wrong position of swab.	• Obvious instruction and indication show on package and Instruction for Use. • Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.
2. Insert the swab into one nostril just until the soft tip is no longer visible. Rotate it in a circle around the inside edge of your nostril 3 times.	USER obtains a medically effective swab for sampling	• USER may use the wrong tip of the swab for sampling. • The swab was inserted too deep into	• Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.

		the nasal cavity.	• Fabrics of swab can protect nasal mucosa.
3. Use the same soft tip to repeat the previous step in the second nostril 3 times.	USER obtains a medically effective swab for sampling.	• USER may use the wrong tip of the swab for sampling. • The swab was inserted too deep into the nasal cavity.	• Indicate the detailed processes and image and in Instruction for Use, assistant with guide video. • Fabrics of swab can protect nasal mucosa.
TEST PROCEDURES 1. Put the swab in the collection tube: The soft tip of the swab that went into your nose should go into the tube first. Soak the swab completely in the solution.	Allow the assay diluent to completely soak the soft tip of the swab and dissolve the probable virus.	• USER may use the wrong tip of the swab go first into extraction tube.	• Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.
2. Rotate and squeeze the swab: rotate and squeeze the soft tip at same time at least 10 times.	Allow the assay diluent to cleave the virus more thoroughly.	• The diluent that containing the virus may spill out. • USER may don't know how to squeeze swab correctly.	• The amount of diluent and the height of the extraction tube are calculated precisely so that even rapid extrusion does not spill out assay diluent. • Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.
3. Then dispose the used swab into biohazard waste bag accord with local legislation.	Dispose clinical waste in safety ways.	• Improper disposal may pose a potential risk of infection to other people who contact with the waste.	• Indicate the detailed processes and image and in Instruction for Use. Assistant with guide video. • Provide a biohazard waste bag.
4. Push cap down firmly and standing: Push the cap straight down onto the dropper. Then place it back to the hole of package and stand for 1 minutes.	Allow assay diluent and the virus fully react, releasing more antigenic proteins.	• The gap between cap and bottle may leak liquid.	• The cap is designed to fit tightly into the tube.
5. Dispense the assay diluent into sample well: Squeeze the dropper and dispense(add) 3 drops of assay diluent straightly into cassette sample well.	Ensure appropriate sample volume onto the membrane as optimized	• Sample volume too high or too low both can't cause best result	• Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.
6. Read result at 15 minutes: Start counting. Read result in 15minutes and interpretate result with instruction.	Wait for the appropriate reaction time and get the correct test result	• USER may misinterpret the results • Time to interpretate result is less than 15 minutes or more than 20 minutes	• Show interpretation result with images and explanation. • Indicate the detailed processes in Instruction for Use.
7. Collect all the package component and sealed in biohazard waste bag: including extraction dropper, swab, test cassette and assay diluent bottle. Discard waste bag accord with local legislation.	Dispose clinical waste in safety ways.	• Improper disposal may pose a potential risk of infection to other people who contact with the waste.	• Indicate the detailed processes and image and in Instruction for Use. Assistant with guide video. • Provide a biohazard waste bag.
QUALITY CONTROL A procedural control is included in the test. A colored line appearing in the control region (C) is considered an	Quality control samples (panel including different COVID-19 concentrations and negative specimens)	• Lack of or inconsistent quality control samples will result in variance of the performance of the	• Indicate the detailed processes in Instruction for Use.

internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.	are used during R & D process and manufacturing to ensure the performance of all the tests.	tests or false results.	
STORAGE AND STABILITY • Test device in the sealed pouch should be stored at 2-30°C. Do not freeze the test device. • The test device should be kept away from direct sunlight, moisture and heat.	The proteins (components) of the assay are sensitive to temperature, light and moisture, their stability should be always maintained to the satisfactory level.	• Performance of the assay can't be ensured; invalid test can mislead the result interpretation and cause harm to the patient	• Indicate the requirement in Instruction for Use.
LIMITATIONS • The contents of this kit are to be used for the qualitative detection of SARS antigens from anterior nasal swab. • Test results must be evaluated in conjunction with other clinical data available to the physicians. • Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result. • A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected improperly. • Positive test results do not rule out co-infections with other pathogens. • Negative test results are not intended to rule out other non-SARS viral or bacterial infections.	USERS shall know the limitation of the assay and make right decision based on the patient conditions.	• Not enough understanding of the limitations of this assay might lead to wrong judgement and decision for the monitoring and treatment of the patients.	• Indicate the detailed processes in Instruction for Use.

6 USABILITY VALIDATION plan

The usability validation plan has been prepared and maintained for NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography). The usability of primary operating functions was validated by quantitative or qualitative method. Several clinical physicians were involved in the validation process. The validation plan can be seen in the following Table 5.
The criteria for validation results of the usability of the primary operating functions can be seen from table 1 to 4.

Table 1.The items and instruction of risk evaluation

Items	Explanation
Severity（S）	5 –very severe, 1 –not severe
Occurrence Probability（O）	5 – often, 1 –never
Risk Level (RL)	Risk Level = Severity ×Occurrence
RRM	Risk Reduction Measure
NH	New hazard generated (no/ yes - if yes, then number of new hazard indicated)
ALOR	Acceptable Level of Risk

Table 2.Classification of Severity Level

Common Term	Description	Symbol	Score
Catastrophic	Result in patient death	S_5	5
Critical	Result in permanent or life-threatening injury.	S_4	4
Serious	Equivocal，difficult to judge whether to requiring professional medical intervention or not	S_3	3
Minor	Result in temporary injury or impairment not requiring professional medical intervention	S_2	2
Negligible	Inconvenience or temporary discomfort	S_1	1

Table 3.Occurrence Probability Level

	Description	Description: in the order of event frequency （times/year）	Symbol	Score
Very High	Failure is almost inevitable	$>10^{-2}$	O_5	5
Fairly high	Likely to happen, often, frequent	10^{-2} - 10^{-3}	O_4	4
High	Repeated failures	10^{-3} - 10^{-4}	O_3	3

Medium	Can happen, but not frequently	10^{-4} - 10^{-5}	O_2	2
Occasional	Occasional failures	〈10^{-5}	O_1	1

Table 4.Acceptable Level of Risk

Risk Level = Severity × Occurrence		
No.	Risk rank	Acceptable level
1	1-4	neglectable risk, no further actions;
2	5-9	moderate risk, preventive action required;
3	10-25	risk is usually not acceptable

Table 5.Usability validation plan and results for NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)

Primary Operation function	Potential USE ERRORS	Usability Evaluation			Validation Measures	Validation Results	Usability Evaluation			ALOR (A/NA)
		S	O	RL			S	O	RL	
Before the test, check the expiration date.	The expired assay kit leads to invalid result	3	2	6	Indicate the requirement in the Instruction for Use.	Instruction for Use	3	1	3	A
TEST PREPARATION Pull up to remove the cap from the extraction dropper: Place it on a clean surface where you can easily find it.	• USERS don't know which is the cap of extraction dropper. • USERS may lose cap of extraction dropper.	3	2	6	• The lid of the extraction dropper is pre-inserted into the tube or choose an integrated product • Remind in the Instruction for Use.	Instruction for Use	3	1	3	A
Dispense assay diluent into extraction dropper: Twist off the cap of assay diluent. Dispense(add) all liquid into extraction dropper.	• USERS may spill out assay diluent.	3	2	6	• The top of the diluent bottle is designed into a narrow structure to ensure smooth and steady liquid flow.	Instruction for Use	3	1	3	A
Place the dropper on the hole of package box: Softly place the extraction dropper on the hole in front surface of package.	• USERS may not find where to put the extraction dropper. • The holes in the package do not allow the tube to be perpendicular to the	3	2	6	• Obvious instruction and indication show on package and Instruction for Use. • The diameter of the hole is designed to be slightly smaller than the diameter		2	1	2	A

	plane or the tube to spill out easily.				of the tube to secure the tube.					
Open the cassette aluminum foil bag: Open the foil bag at notch part. Place cassette on a plat surface.	• USERS may don't know how to open an aluminum foil bag. • USERS may place the test card on the bevel and result in incorrect test results	3	2	6	• Notches and indication are designed at the edge of the pouch to ease the opening. • Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.	Instruction for Use	3	1	3	A
SPECIMEN COLLECTION Anterior nasal swab Open the package with the swab: Peel open where indicated. Pull swab out of its packaging.	• USER may hold swab upside down. • USER may touch the soft tip of swab and pollute it.	2	2	4	Indicate the detailed processes and image and in Instruction for Use. Assistant with guide video.	Instruction for Use QR code printed on package and Instruction for Use.	2	1	2	A
Insert the swab into one nostril just until the soft tip is no longer visible. Rotate it in a circle around the inside edge of your nostril 3 times.	• USER may use the wrong tip of the swab for sampling. • The swab was inserted too deep into the nasal cavity.	3	2	6	Indicate the detailed processes and image and in Instruction for Use. Assistant with guide video.	Instruction for Use QR code printed on package and Instruction for Use.	3	1	3	A
Use the same soft tip to repeat the previous step in the second nostril 3 times.	• USER may use the wrong tip of the swab for sampling. • The swab was inserted too deep into the nasal cavity.	3	2	6	Indicate the detailed processes and image and in Instruction for Use. Assistant with guide video.	Instruction for Use QR code printed on package and Instruction for Use.	3	1	3	A
TEST PROCEDURES Put the swab in the collection tube: The soft	• USER may use the wrong	3	2	6	• Indicate the detailed processes	Instruction for Use QR code	3	1	3	A

tip of the swab that went into your nose should go into the tube first. Soak the swab completely in the solution.	tip of the swab go first into extraction tube.				and image and in Instruction for Use, assistant with guide video.	printed on package and Instruction for Use.				
Rotate and squeeze the swab: rotate and squeeze the soft tip at same time at least 10 times.	• The diluent that containing the virus may spill out. • USER may don't know how to squeeze swab correctly.	3	3	9	• The amount of diluent and the height of the extraction tube are calculated precisely so that even rapid extrusion does not spill out assay diluent. • Indicate the detailed processes and image and in Instruction for Use, assistant with guide video.	Instruction for Use QR code printed on package and Instruction for Use. Waste bag	2	2	4	A
Then dispose the used swab into biohazard waste bag accord with local legislation.	• Improper disposal may pose a potential risk of infection to other people who contact with the waste.	4	2	8	• Indicate the detailed processes and image and in Instruction for Use. Assistant with guide video. • Provide a biohazard waste bag.	Instruction for Use Package	2	1	2	A
Push cap down firmly and standing: Push the cap straight down onto the dropper. Then place it back to the hole of package and stand for 1 minutes.	• The gap between cap and bottle may leak liquid.	3	2	6	• The cap is designed to fit tightly into the tube.	Instruction for Use QR code printed on package and Instruction for Use.	3	1	3	A
Dispense the assay diluent into sample well: Squeeze the dropper and dispense(add) 3 drops of assay diluent straightly into cassette sample well.	• Sample volume too high or too low both can't cause best result.	3	2	6	• Indicate the detailed processes and image and in Instruction for Use,	Instruction for Use QR code printed on package and	3	1	3	A

					assistant with guide video.	Instruction for Use.				
Read result at 15 minutes: Start counting. Read result in 15minutes and interpretate result with instruction.	• USER may misinterpret the results • Time to interpretate result is less than 15 minutes or more than 20 minutes	2	2	4	• Show interpretation result with images and explanation. • Indicate the detailed processes in Instruction for Use.	Instruction for Use QR code printed on package and Instruction for Use.	2	1	2	A
Collect all the package component and sealed in biohazard waste bag: including extraction dropper, swab, test cassette and assay diluent bottle. Discard waste bag accord with local legislation.	• Improper disposal may pose a potential risk of infection to other people who contact with the waste.	4	2	8	• Indicate the detailed processes and image and in Instruction for Use. Assistant with guide video. • Provide a biohazard waste bag.	Waste bag	2	1	2	A

7 USER INTERFACE design and implementation

The user interface design can be seen in the risk management report.

8 USABILITY VERIFICATION

The usability verification can be seen in the risk management report.

9 USABILITY VALIDATION

The validation results can be seen in table 5.

10 Conclusion

All of factors affecting the usability have been evaluated and some measures are taken to assure the usability according to EN 62366-1:2015. The results indicate that the NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) produced by Atlas Link Technology Co., Ltd is safe and effective in use.