SARS-CoV-2 Antigen Rapid Test

Analytical Specificity Study Report

Final report date: 2020-09-02

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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

Signature: 5.1.2e

Company: **Atlas Link Technology Co.,Ltd**

Position: **Head of R & D Department**

Verification Dates:2020-09-02

Study Summary

All cross-reaction specimens were tested with NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography). No cross-reaction was observed. The results demonstrated that NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) has good analytical specificity.

1. Purpose

Study on a panel of high prevalence respiratory pathogens that could potentially cross-react with test and estimate these pathogens are not influence the result.

2. Reference and Compliance

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

3. Materials

- Pathogen materials (Working concentration refer to form below)
- NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), Lot No.: 20200323, Production Date: 2020-03-23
- NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), Lot No.: 20200324, Production Date: 2020-03-24
- NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography), Lot No.: 20200325, Production Date: 2020-03-25
- SARS-CoV-2 Virus (2.5×10^5 $TCID_{50}$/mL)
- Assay diluent, Lot No.: 20200323, 20200324, 20200325.

Pathogen materials

Type	cross-reactivity specimens	Concentration
Nasal Wash	Pooled human nasal wash	N/A
Virus	Human metapneumovirus (hMPV)	1.0 x 10^5 $TCID_{50}$/ml
	Human coronavirus 229E	1.0 x 10^5 $TCID_{50}$/ml
	Human coronavirus OC43	1.0 x 10^5 $TCID_{50}$/ml
	Human coronavirus NL63	1.0 x 10^5 $TCID_{50}$/ml
	Adenovirus	1.0 x 10^5 $TCID_{50}$/ml
	Parainfluenza virus 1	1.0 x 10^5 $TCID_{50}$/ml
	Parainfluenza virus 2	1.0 x 10^5 $TCID_{50}$/ml
	Parainfluenza virus 3	1.0 x 10^5 $TCID_{50}$/ml
	Parainfluenza virus 4	1.0 x 10^5 $TCID_{50}$/ml
	Influenza A	1.0 x 10^5 $TCID_{50}$/ml
	Influenza B	1.0 x 10^5 $TCID_{50}$/ml
	Enterovirus	1.0 x 10^5 $TCID_{50}$/ml
	Respiratory syncytial virus	1.0 x 10^5 PFU/ml
	Rhinovirus	1.0 x 10^5 PFU/ml
Bacteria	Haemophilus influenzae	1.0 x 10^6 CFU/ml
	Streptococcus pneumoniae	1.0 x 10^6 CFU/ml
	Streptococcus pyogenes	1.0 x 10^6 CFU/ml

	Candida albicans	1.0 x 10^6 CFU/ml
	Bordetella pertussis	1.0 x 10^6 CFU/ml
	Mycoplasma pneumoniae	1.0 x 10^6 U/ml
	Chlamydia pneumoniae	1.0 x 10^6 CFU/ml
	Legionella pneumophila	1.0 x 10^6 CFU/ml

4. Study Design:

Cross-reactivity and potential interference of NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) was evaluated by testing the pathogenic microorganisms listed in the table above.

Each of the organisms were tested in triplicate in the absence or presence of heat-inactivated SARS-CoV-2 virus at 3x LoD for each lot, and three random lots were used. The test kits were all randomly selected from the three lots.

5. Evaluation Criteria

Negative

If only the C band is present, the absence of any burgundy color in the test band indicates that no SARS-CoV-2 antibody is detected in the specimen. The result is negative.

Positive

In addition to the presence of C band, if test band is developed, the test indicates for the presence of SARS-CoV-2 total antibody. The result is positive.

Positive（+++）: Both C and T lines appear regardless of color intensity. T line strong

Positive（++）: Both C and T lines appear regardless of color intensity. T line medium

Positive（+）: Both C and T lines appear regardless of color intensity. T line weak

Invalid

If no C band is developed, the assay is invalid regardless of any burgundy color in the test bands as indicated below. Repeat the assay with a new device.

6. Results

The results demonstrated that NOVA Test®SARS-CoV-2 Antigen Rapid Test kits have no significant cross-reactivity with these specimens (1 nasal wash,14 viruses, 8 bacteria).

Table 1- Results of cross-react with only pathogens

cross-reactivity specimens	SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography)		
	20200323	20200324	20200325
Pooled human nasal wash	3/3(-)	3/3(-)	3/3(-)

Human metapneumovirus (hMPV)	3/3(-)	3/3(-)	3/3(-)
Human coronavirus 229E	3/3(-)	3/3(-)	3/3(-)
Human coronavirus OC43	3/3(-)	3/3(-)	3/3(-)
Human coronavirus NL63	3/3(-)	3/3(-)	3/3(-)
Adenovirus	3/3(-)	3/3(-)	3/3(-)
Parainfluenza virus 1	3/3(-)	3/3(-)	3/3(-)
Parainfluenza virus 2	3/3(-)	3/3(-)	3/3(-)
Parainfluenza virus 3	3/3(-)	3/3(-)	3/3(-)
Parainfluenza virus 4	3/3(-)	3/3(-)	3/3(-)
Influenza A	3/3(-)	3/3(-)	3/3(-)
Influenza B	3/3(-)	3/3(-)	3/3(-)
Enterovirus	3/3(-)	3/3(-)	3/3(-)
Respiratory syncytial virus	3/3(-)	3/3(-)	3/3(-)
Rhinovirus	3/3(-)	3/3(-)	3/3(-)
Haemophilus influenzae	3/3(-)	3/3(-)	3/3(-)
Streptococcus pneumoniae	3/3(-)	3/3(-)	3/3(-)
Streptococcus pyogenes	3/3(-)	3/3(-)	3/3(-)
Candida albicans	3/3(-)	3/3(-)	3/3(-)
Bordetella pertussis	3/3(-)	3/3(-)	3/3(-)
Mycoplasma pneumoniae	3/3(-)	3/3(-)	3/3(-)
Chlamydia pneumoniae	3/3(-)	3/3(-)	3/3(-)
Legionella pneumophila	3/3(-)	3/3(-)	3/3(-)

7. Conclusion

All cross-reaction specimens were tested with NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography). No cross-reaction was observed. The results demonstrated that NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) has good analytical specificity.

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.