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

CE IVD REF nCov-500

INTENDED USE

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 Nasal swab (NS) and Oropharyngeal swab (OP swab) specimens from patients who are suspected of COVID-19 by a healthcare provider. Performance of the test is limited to professional use.

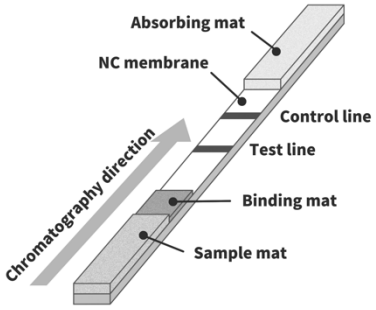
SARS-CoV-2 Antigen Rapid Test Kit provides preliminary test results, with negative results don't preclude SARS-CoV-2 infection. The test kit cannot be used as the sole basis for treatment or other management decision. **For *in vitro* diagnostic use only.**

SUMMARY

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.

PRINCIPLES OF THE TEST



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 Nasal swab (NS) and Oropharyngeal swab (OP 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.

MATERIAL PROVIDED

- Test Cassettes (20×)
- Assay Diluent [6ml/bottle] (2×)
- Sterile Nasal Swabs (20×)

Or Sterile Oropharyngeal Swabs (20×)

- Disposable Extraction Droppers (20×)
- Workstation/Rack (1×)
- Instruction for Use (1×)

Type of sterile swabs will be provided according to customer's demand.

MATERIAL REQUIRED BUT NOT PROVIDED

- Timer/Watch
- Personal protective equipment, such as protective gloves, medical mask, goggles and lab coat
- Appropriate biohazard waste container and disinfectants

WARNINGS AND PRECAUTIONS

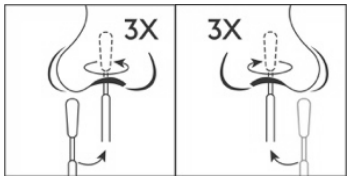
1.For *in vitro* diagnostic use.
2.To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
3.When collecting a sample, use the swab supplied in the kit. Use of alternative swabs may result in false negative results.
4.Do not touch the reaction area of test strip.
5.Do not use test kit beyond the expiration date.
6.Do not use the kit if the pouch is punctured or sealed not well.
7.Performance of the test should be applied by professionally trained staff working in certified laboratories or clinics.
8.The test result should be interpreted by the physician along with clinical findings and other laboratory test results.
9. Dispose of cassette and items in contact with samples as medical waste after use.
10.Do not freeze the cassette or any other material.

STORAGE AND STABILITY

The kit is stored at 2 ~ 30 °C in sealed, preserve avoid light. The validity period is now at 18 months, can be extended if new stability data are available.
Reagents and devices must be used at room temperature (15–30 °C).
The unsealed cassette is valid for 1 hour. It is recommended to use the testing kit immediately after opening, especially the test environment humidity is more than 60%. The expiration date is printed on the package.

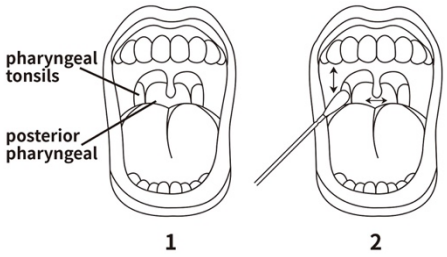
SPECIMEN COLLECTION

Anterior Nasal Swab (NS):



Use the nasal swap provided in the kit.
1. 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 nostril 3 times.
2. Use the same soft tip to repeat the previous step in the second nostril 3 times.

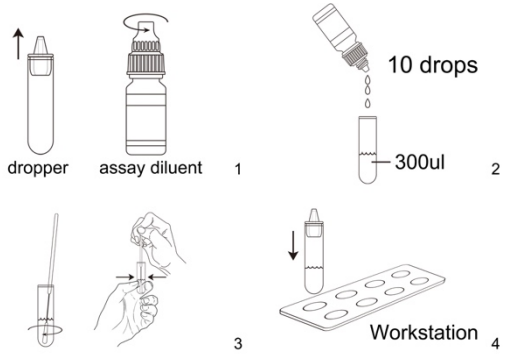
Oropharyngeal Swab (OP Swab):



1.Gently lift the individual's head, ask for open the mouth until expose the pharyngeal tonsils on both sides.
2.Wipe the base of the tongue with a cotton swab, gently wiping pharyngeal tonsils back and forth on both sides at least 3 times,

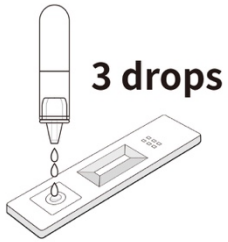
and then wiping the posterior pharyngeal wall up and down at least 3 times.

SAMPLE PREPARATION



1.Twist off the caps of the extraction dropper and the Assay Diluent bottle.
2. Take Assay Diluent bottle and dispense 10 drops (about 300μL) extract solution into the dropper
3.Soak the swab completely in the solution, rotate and squeeze at same time at least 10 times. Then dispose the used swab properly as medical waste.
4.**Close the cap**, blend extract solution and place it on the workstation/rack for 1min.

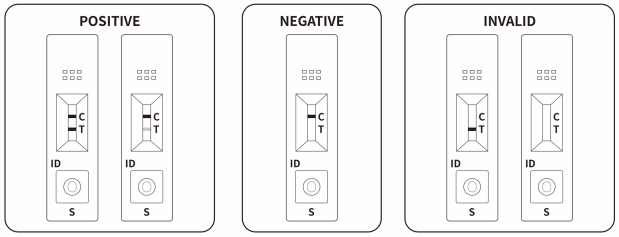
TEST PROCEDURES



Before the test, carefully read the kit instructions and strictly follow it.
1.Unpack the cassette aluminum foil bag, take out the cassette and lay it on the flat platform.
2.Turn upside down the dropper prepared from the SAMPLE PREPARATION, dispense 3 drops of the specimen processing solution (70-80μL) vertically into the cassette sample well (S sign).
3. Placed the cassette at room temperature for 15 minutes then read the test result.

Warning: Results must be interpreted in 20 minutes after completing the testing procedure.

INTERPRETATION OF RESULT



1.Positive: Two red ribbon, the test line (T line) and the quality control line (C line) are colored.
2. Negative: One red ribbon, just quality control line (C line) is colored;
3. Invalid: No color appears in the position of the quality control line (C line) in the observation window, indicating that this test is invalid and should be resampled for testing.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

LIMITATION

1. The contents of this kit are to be used for the qualitative detection of SARS antigens from nasal swab or oropharyngeal swab specimens.
2. Test results must be evaluated in conjunction with other clinical data available to the physicians.
3. Failure to follow the Test Procedure may adversely affect test performance and / or invalidate the test result.
4. 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.
5. Positive test results do not rule out co-infections with other pathogens.
6. Negative test results are not intended to rule in other non-SARS viral or bacterial infections.

PERFORMANCE CHARACTERISTICS

Clinical Performance

228 samples were collected from selected subjects, all samples were tested with SARS-CoV-2 Antigen Rapid Test Kit and SARS-COV-2 R-GENE® - Real Time Detection kit produced by BioMérieux. Calculated the specificity and sensitivity, the results are as follows：

BioMérieux	NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit		Total
	Positive	Negative	
Positive	64	1	65
Negative	2	161	163
Total	66	162	228

Diagnostic Sensitivity:
64/(1+64)×100%=98.5% 95%CI(91.8%-99.7%)
Diagnostic Specificity:
161/(2+161)×100%=98.8% 95%CI(95.6%-99.7%)
Overall Agreement:
(64+161)/228×100%=98.7%. 95%CI(96.2%-99.6%)

228 samples were collected from selected subjects, all samples were tested with SARS-CoV-2 Antigen Rapid Test Kit and the BD Veritor™ System for Rapid Detection of SARS-CoV-2 produced by BD Biosciences. Calculated the specificity and sensitivity, the results are as follows:

BD Biosciences	NOVA Test® SARS-CoV-2 Antigen Rapid Test Kit		Total
	Positive	Negative	
Positive	65	1	66
Negative	1	161	162
Total	66	162	228

Diagnostic Sensitivity:
65/(1+65)×100%=98.5% 95%CI(91.9%-99.7%)
Diagnostic Specificity:
161/(1+161)×100%=99.4% 95%CI(96.6%-99.9%)
Overall Agreement:
(65+161)/228×100%=99.1%. 95%CI(96.9%-99.8%)

Analytical Performance

Analytical Sensitivity (Limit of Detection, LoD)

The Limit of Detection (LoD) of the NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit was determined using limiting dilutions of heat-inactive SARS-CoV-2, that has been inactivated by heating at 65°C for 30 minutes. The material was supplied at a concentration of $2.5x10^5$ $TCID_{50}$/ml.

In this study, designed to estimate the LoD of the assay when using a direct nasopharyngeal swab, the starting material was spiked into a volume of pooled human nasal matrix obtained from healthy donors and confirmed negative for SARS-CoV-2. The specimen samples were prepared into to 3-4 folds dilutions series. At each dilution, 50μl samples were added to swabs and then tested in the NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit using the test procedure according to instruction for use.

Starting Material Concentration	Diluent Concentration				
2.5×10^5 $TCID_{50}$/mL	200	150	100	50	25
Positive/Total	20/20	20/20	20/20	20/20	14/20

Results indicate that the LoD of NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) is 50 $TCID_{50}$/ml.

Analytical Specificity (Cross-Reactivity and Microbial Interference)

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 below.

Type	Pathogens	Concentration
Nasal Wash	Pooled human nasal wash	N/A
Virus	MERS	1.0 x 10^5 $TCID_{50}$/ml
	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
	Human coronavirus HKU1	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	Hemophilus 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

Testing was performed in triplicate.

Based on the date generated by this study, the organisms or viruses tested NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit do not cross-react or interfere.

Interfering Substances

A study was performed demonstrate that the potentially interfering substances that may be found in the upper respiratory tract do not cross-react or interfere with the detection of SARS-CoV-2 in the NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit.

Endogenous Interference substances	Concentration
Acetaminophen	20 mg/dL
Acetylsalicylic acid	20 mg/dL
Ascorbic acid	20 mg/dL
Caffeine	20 mg/dL
Gentesic acid	20 mg/dL
Phenylpropanolamine	20 mg/dL
Salicylic acid	20 mg/dL
EDTA	80 mg/dL
Benzoylecgonine	10 mg/dL
Atropine	20 mg/dL
Cannabinol	10 mg/dL
Ethanol	1% v/v
Methanol	1% v/v
Albumin	2,000mg/dL
Glucose	2,000mg/dL
Bilirubin	1,000mg/dL
Hemoglobin	1,000mg/dL
Triglyceride	50 mg/dL
Total cholesterol	6mmol/L

Based on the date generated by this study, the endogenous substances tested NOVA Test®SARS-CoV-2 Antigen Rapid Test Kit do not cross-react or interfere.

Hook Effect

The highest concentration of heat-inactivated SARS-CoV-2 stock available 2.5×10^5 $TCID_{50}$/ml was tested. There was no Hook effect detected.

REFERENCE

1.Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Ade Virus Res 211;81:85-164
2.Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. Trends Microbiol 2016;24:490-502
3.Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol2019;17:181-192.
4.World Health Organization(WHO). Coronavirus. http://www.who.int/health-topics/coronavirus

INDEX OF SYMBOLS

	Manufacture
	*In vitro* diagnostic medical device
	Authorized representative in the European Community
	Caution
	Use-by date
	Batch Code
	Catalogue Number
	Store between 2 – 30 centigrade

	Contains sufficient for <n> tests
	Do Not Reuse
	Consult Instructions for Use
	Do Not use if package is damaged
	CE-Mark

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