Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)

For professional use only limited to laboratories certified to perform high complexity testing, including testing at the point-of-care when the site is covered by the laboratory's CLIA certificate for high-complexity testing

Package

25 Tests /Box

Intended use

The Novel Coronavirus (COVID-19) Antigen Test Kit (NC-ATK) is a lateral flow immunoassay of nucleocapsid protein antigen from SARS-CoV-2 intended to be used for the qualitative detection of novel coronavirus antigen in human throat swabs or nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. It is intended to be used in the clinical laboratory as an aid in the diagnosis of infection of novel coronavirus.

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Coronavirus (CoV) is a member of the family Coronavirus, which classifies α、β、γ. α、β are only pathogenic to mammals, γmainly cause avian infections. CoV are mainly spread by direct contact with secretions or by aerosol and droplets, and there is also evidence that they also can be spread by the excrement.There are seven types of human coronaviruses (HCoV), which are important pathogen of human respiratory infections that can cause human respiratory diseases, HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HcoV-HKU1, MERS-CoV, andnovelcoronaviruses (2019-nCoV).Among them,the clinical manifestations of novelcoronavirus (2019-nCoV) are systemic symptoms such as fever and fatigue, accompanied by dry cough and dyspnea. It can quickly develop into severe pneumonia, respiratory failure, acute respiratory distress syndrome, septic shock, multiple organ failure, severe acid-base metabolism disorders, etc., are even life-threatening.

Test principle

The NC-ATK employs colloidal gold immunochromatography technology. The NC-ATK contains 1) recombinant Novel Coronavirus (2019-nCoV) monoclonal antibody with gold labeling and 2)a quality control antibody gold marker. The nitrocellulose membrane is fixed with the detection line (T line) and one quality control line (C line). The monoclonal antibody for 2019-nCoV was fixed on the T line. Line C is fixed with quality control antibody (a goat anti-rabbit IgG.) During testing, the Nasopharyngeal swab/Oropharyngeal swab specimen eluate reacts with recombinant monoclonal antibody conjugated with colloidal gold. The sample migrates on the membrane chromatographically by capillary action to react with the 2019-nCoV antibody on the membrane. If the sample contains SARS-COV-2 antigen, the antigen will be combined with a monoclonal antibody of colloidal gold labeled novel coronavirus. The immune complex will be membrane fixed and form ared line.This display will be coronavirus antigen positive. If the line does not develop color, a negative result will be indicated.The test card also contains a quality control line C, which should appear red regardless of whether there is a positive sample detection line. This serves as an internal control and indicates that the proper volume of specimen has been added and membrane wicking has occurred. If the control line does not appear, the test result is invalid and the sample must be re-tested.

Materials provided

Contents

25	Test cards
25	Antigen extraction tubes
1	Antigen extraction reagent R1vial
25	Swabs (Nasopharyngeal swab/ Oropharyngeal swab)

Additional materials required but not provided

Timer

One test card contains:

Recombinant novel coronavirus monoclonal antibody and rabbit IgG antibody

Novel coronavirus monoclonal antibody for T line

Goat-anti-rabbit IgG antibody for C line

Antigen extraction reagent R1: Sodium chloride, Sodium phosphate, Sodium casein salt

Storage and stability

Sealed: The kit must be stored at 4-30℃, valid for 24 months.Keep dry.

Opened: Thetest card must be used within 1 hour once its foil pouch is opened.

Sample collection and preparation

1. ***Oropharyngeal swab***:

Have the patient's head slightly tilted back, mouth open, and "ah" sound, exposing both sides of the pharyngeal tonsils. Use a hand swab to gently wipe the pharyngeal tonsils on both sides of the patient for at least 3 times, and then wipe them on the posterior pharyngeal wall for at least 3 times.Place the swab specimen into the pre-added extract tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab.

2. ***Nasopharyngealswab***:

Allow the patient's head to relax naturally, and slowly rotate the swab against the nostril wall into the nostril of the patient to the nasal palate, and then slowly rotate it out while wiping.Wipe the other nostril with the same swab, using the same method. Place the swab specimen into the pre-added extract tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigens in the swab.

Test method

The test method is colloidal gold.

Test procedure

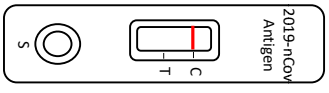
1. Open the package and take out the test card.
2. Place the extraction tube on the workbench.The swab extractor bottle (R1) is pressed vertically downward to allow the solution to drip freely into the extractor tube without touching the edge of the tube. Add 6 drops of R1 to the extractor tube.
3. Put the swab specimen into the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.Squeeze the swab over the head to remove as much liquid as possible from the swab.Dispose of swabs according to biohazard waste disposal method.
4. Install the cap on the extraction tube, put two drops into the sample hole of the test card, and start the timer.

Notes:Applying sufficient amount of sample extraction liquid is essential for a valid test result. If migration (the wetting of membrane) is not observed in the test window after one minute, add one more drop to sample well.

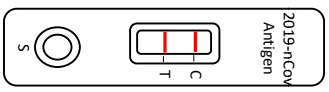
5. Read the results in 20 minutes.A strong positive result can be reported within 20 minutes, but a negative result must be reported after 20 minutes, and the result after 30 minutes is no longer valid.

Explanation of results

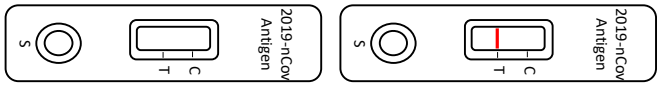
1. Negative results: One color line appears in the control region (C). No apparent red line appears in the test region (T). (As Below)



2. **Positive results**: Two distinct colored lines appear. One color line should be in the control region (C) and another color line should be in the test region (T), means positive.(As Below)



3. **Invalid result:** If the Quality Control Line C is not observed, the detection should be repeated regardless of whether or not the detection line is displayed. (As Below)



Clinical Performance Data*

Method		PCR Test		Total Results
Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	Results	Positive	Negative	
	Positive	72	0	72
	Negative	3	220	223
Total Results		75	220	295

Relative Sensitivity: 72/75	96.00% (88.75%～99.17%)
Relative Specificity:220/220	100.00% (98.34%～100.00%)
Accuracy: 292/295	98.98% (97.06%～99.79%)

Number of Days Post-onset of Patient Symptoms

Days Post Symptom Onset	Cumulative RT-PCR Positive	Cumulative Antigen Positive	PPA	95 % Confidence Interval	
1	17	17	100.00%	80.50%	100.00%
2	28	28	100.00%	87.70%	100.00%
3	38	38	100.00%	90.80%	100.00%
4	58	58	100.00%	93.80%	100.00%
5	75	72	96.00%	88.80%	99.20%

Performance against the Comparator Method by Cycle Threshold Counts

Norman Novel Coronavirus (2019-nCoV) Antigen Testing Kit (Colloidal Gold)	(POS by Ct Category)	
	POS (Ct < 33)	POS (Ct ⩾ 33)
Positive	*62*	*10*
Negative	*0*	*3*
Total	*62*	*13*
Positive Agreement (95% CI)	*100.0 (94.2, 100.0)*	*76.92 (46.2, 95.0)*

Positive Results by Patient Age

Age	Total #	PCR Positive	Prevalence
⩽5 years	0	0	0%
6 to 21 years	11	2	18.20%
22 to 59 years	204	58	28.40%
⩾ 60 years	80	15	18.80%

Concordance between results with nasopharyngeal and oropharyngeal swab specimens. The concordance between specimen types was shown to be 100%; however, the qualitative intensity of the T line signal was subjectively lower with oropharyngeal swab specimens in 5 of the 20 paired positive specimens tested.

*Additional details regarding the performance characterization of the test can be found at http://www.nrmchina.com/en/index.php?case=archive&act=show&aid=216

Limitation of the procedure

1. The testis for in vitro diagnostics only.
2. This reagent is only used with samples fromhuman oropharyngeal swabs or nasopharyngeal swabs samples. The test has not been validated with sample sources other than those indicated in this instruction for use. Use of other sample sources may result in incorrect test results.
3. This reagent is only used for qualitative testing and does not indicate the number ofnovel coronavirus antigen in the sample.
4. This reagent is only a clinical ancillary diagnostic tool. If the results are positive, it is recommended to use other methods for further examination and to follow the doctor's diagnosis.
5. The test results of this product are for clinical reference only and should not be used as the sole basis for clinical diagnosis and treatment. The clinical management of patients should be combined with their symptoms, signs, medical history, other laboratory examinations, treatment response and epidemiology.

Warnings and precautions

For *in vitro* diagnostic use.

The package insert must be carefully followed. Reliability ofthe test results cannot be guaranteed if there are any deviations from the package insert.

Safety precautions

CAUTION: This product requires the handling of human samples. It is recommended that all human sourced materials are considered potentially infectious and be handled in accordance with the OSHA Standard on Bloodborne Pathogens. Biosafety Level 211 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents. Appropriate protective measures should be taken in the collection, processing, storage, mixing of the sample and testing process; if the sample and the reagent contact skin, wash with plenty of water. If skin irritation or rash occurs, get medical advice/attention. Samples,used cartridge and disposable tips may be potentially infectious. Proper handling and disposal methods should be established by the laboratory in accordance with local regulations.Testing should be conducted by professionally trained staff working in certified laboratories or clinics at which the sample(s) is taken by qualified medical personnel.

Precautions and notices

1. Read the instructions carefully before using the kit, and strictly control the reaction time. If you do not follow the instructions, you will get inaccurate results.
2. The sample shall be testedin a laboratory under the described precautions and conditions. All samples and materials during testing should be handled in accordance with the laboratory practice for infectious diseases.
3. Guard against moisture, do not open the aluminum foil bag before it is ready for testing. Do not use the aluminum foil bag if it is damaged or the test card is damp.
4. Please use it within the validity period.Do not use the kit beyond the expiration date. The production date and expiration date are on the label.
5. Bring all reagents and samples to room temperature (15～30℃) before use.Please avoid high temperature in the lab.
6. Do not replace the components in this kit with components in other kits.Different batches of antigen extract R1 and test cardcannot be mixed.
7. Do not dilute the sample for testing, otherwise you may get inaccurate results.
8. The kit shall be stored in strict accordance with the conditions specified in this manual. Please do not store the kit under freezingconditions.
9. The test methods and results must be interpreted in strict accordance as described in the instructions for use.
10. The test cardis a single use card; should not be reused and should follow disposal per guidelines for infectious disease materials.
11. Negative results will occur with this kit if the novel coronavirus antigen titer in the sample falls below the minimum detection limit for this kit.
12. To avoid contamination, wear clean gloves when testing kits and samples.
13. **Do not use PCR sample preservation solution (viral transport medium) for the antigen test kit**. The sample must be treated instead with the antigen extraction reagent R1 from the kit. Otherwise, it will cause denaturation of viral protein and the antigen cannot be detected.
14. Quality Control(QC) should be a part of the quality management system for each individual laboratory. The manufacturer has an internal control built into the test cartridge. This control must be positive for the test to be valid. Additionally, Norman has a positive and negative QC product that is available for purchase to be used by laboratories if additional quality control material is needed.

Norman recommends that laboratories should run the quality control products in accordance with their established quality management system guidance or at minimum when parameters have changed that may affect the assay performance.

These parameters should include but not be limited to: 1. Change of lot number of test kit; 2. Training of new personnel; 3. Suspected change in storage or shipping conditions exceeds manufacturer's supported claims; 4. Suspected change in testing environment exceeds manufacturer's supported claims.

Basic information

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