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Novel Coronavirus(2019-nCoV) Antigen Rapid Test

Overview

COVID-19 is caused by the virus severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and is primarily transmitted from person-to-person through respiratory droplets. The estimated incubation period for COVID-19 is up to 14 days from the time of exposure, with a median incubation period of 4 to 5 days.

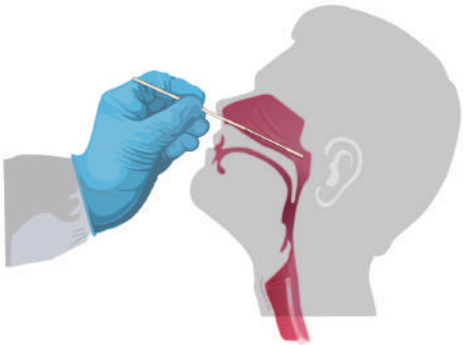
Antigen is generally detectable in upper respiratory specimens during the acute phase of infection. This rapid test represents a valuable alternative in the context of a global shortage of diagnostic tests and allows to obtain results quickly and reliably.

Advantage of Antigen Test

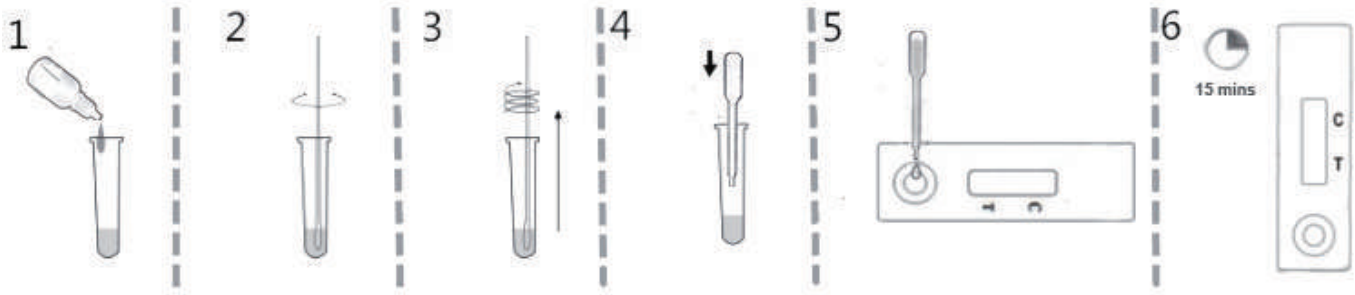
- **Early detection**
- **Simple operation**
- **Fast result within 15 minutes**
- **Detection without any equipment**

Novel Coronavirus(2019-nCoV) Antigen Rapid Test

Sample collection



Test procedure



1. Add 15 drops of the buffer into the extraction tube.
2. Insert the specimen collection swab into the buffer and rotate the swab constantly.
Repeat several times and process for 2 minutes.
3. Squeeze the swab on the tube wall so that the liquid is extruded continuously.
Take out the sample and discard the swab.
4. Use the pipette to fully suck the sample treatment fluid.
5. Dispense 3 drops from the extraction tube into the sample well of the tested card.
6. Wait 15 minutes to interpret and record the test result.

Interpretation of Result

Clinical Study

Novel Coronavirus Antigen Rapid Test	PCR test result	
	Negative	Positive
Negative	198	10
Positive	2	70
Specificity	99.00%	
Sensitivity	90.91%	
Accuracy	96.75%	

Packing Information

Product	Specification	Carton
Novel Coronavirus(2019-nCoV) Antigen Rapid Test	50T/kit	74.5*59.5*31cm 40kits/ctn 23kg
Novel Coronavirus(2019-nCoV) Antigen Rapid Test	25T/kit	74.5*31*16.5cm 20kits/ctn 6.5kg

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Novel Coronavirus(2019-nCoV) Antigen Rapid Test

Package Insert

【PRODUCT NAME】

Novel Coronavirus(2019-nCoV) Antigen Rapid Test

【PACKING SPECIFICATIONS】

25 tests/ kit,50 tests/ kit.

【INTENDED USE】

This kit is used for in vitro qualitative detection of novel coronavirus (2019-CoV) antigens in human throat swabs and nasal swab samples, and is used for clinical auxiliary diagnosis of novel coronavirus infection. It cannot be used as a basis for diagnosis and exclusion of new coronavirus infection.

【TEST PRINCIPLE】

This kit uses immunochromatography method. When the sample to be tested is added to the test card, if there is a novel coronavirus (2019-nCOV) antigen in the sample, it will be combined with the colloidal gold-labeled 2019-CoV antibody. The immune complex is Moving forward along the detection card under capillary action, it will form a red band (T line) with the 2019-nCoV coating antibody coated in the detection area on the membrane, and the colloidal gold-labeled biotin is coated with streptomyces The quality control area of prime avidin was captured, forming a red band (line C), showing positive for the new coronavirus (2019-nCOV) antigen.

【THE MAIN COMPONENTS】

	Components	Specification 25 tests/kit	50 tests/kit	Main Activeingredients
1	Test card	25 pieces	50 pieces	The detection area is coated with 2019-nCoV antibody, the quality control area is coated with streptavidin, and the binding pad contains colloidal gold labeled 2019-nCoV antibody.
2	Sample treatment solution	500μL/vial* 25vials	500μL/vial*50vials	Surfactant,ProClin300

Components in different batches of kits cannot be used interchangeably.

【STORAGE CONDITIONS AND VALIDITY】

Store at 2 ~ 30 ℃, the validity period is tentatively 18 months.

After opening the test card, it should be used as soon as possible within 1 hour. The sample treatment solution should be capped immediately after opening, and placed in a cool place, away from direct sunlight.

See the product label for the production date and duration of use.

【SAMPLE REQUIREMENTS】

◆ Applicable sample types：Oropharyngeal swab, Nasopharyngeal swab

◆ Sample collection and preparation

1 Oropharyngeal swab collection method: the sampled person's head is slightly tilted, and the mouth is opened wide, exposing the pharyngeal tonsils on both sides. Wipe the base of the tongue with a swab, gently wipe the pharyngeal tonsils on both sides of the sampled person at least 3 times, and then wipe the posterior wall of the pharyngeal up and down at least 3 times.

2 Nasopharyngeal swab collection method: the sampler gently supports the head of the sampled person with one hand, and holds the swab with the other hand, inserts the swab through the nostril, and then penetrate back slowly along the bottom of the lower nasal cavity, avoiding vigorously to avoid traumatic bleeding. When the tip of the swab reaches the back wall of the

nasopharyngeal cavity, rotate it once (to prevent reflex cough, stop for one minute), and then slowly remove the swab.

3 Saliva collection method: No eating or drinking within 30 minutes before collection. Use a medical disposable sampling swab to gently press and turn the buccal swab on the back of the tongue or on the mucous membrane of the buccal cavity (both cheeks inside the mouth) and turn the swab 3-5 times.

◆ Sample processing:

1 Add 500 microliters of sample treatment solution to the sampling tube (aliquoted sample treatment solution can also be provided), immerse the sampled swab into the sample treatment solution, make the sample treatment solution completely penetrate the swab, rotate and squeeze the swab 10 times, then remove the swab and take out the remaining liquid for sample testing.

◆ Sample storage:

Store in a dry, sterile airtight condition, on ice or at 4°C for a short time.

【TESTING METHOD】

1 Take out the test card, equilibrate to room temperature, open the aluminum foil bag of the test card, and place it flat on the desktop.

2 Drop 2-3 drops (80-100μL) of the processed sample treatment solution vertically into the sample hole of the test card.

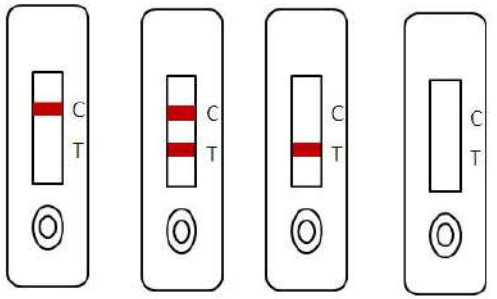
3 The test card is placed at room temperature for 15 minutes to observe the test result. If it is observed for more than 30 minutes, the result is invalid.

【INTERPRETATION OF THE TEST RESULTS】

1 Negative result: A red line, only a red reaction line appears in the quality control area C, as shown in the following figure (a);

2 Positive result: Two red lines,a red reaction line appears in the detection area T and the quality control area C, as shown in the following figure (b);

3 Invalid result: When the quality control line C cannot be observed, no matter whether T appears or not, it is an invalid result. As shown in the following figure (c/d) ,it should be retested.



a)Negative b)Positive c)Invalid d)Invalid

◆ Please pay attention to the experimental process

1 Continuity of operation is required.

2 The test card must be kept in a sealed aluminum foil bag unless it is ready for immediate use. Once the aluminum foil bag is opened, it should be used within 1 hours. After use, please discard it and do not reuse it.

【PERFORMANCE INDICATORS】

◆ Negative reference product compliance rate:Negative reference product compliance rate（-/-）should be 20/20；

◆ Positive reference product compliance rate:Positive reference product compliance rate（+/+）should be 8/8；

◆ Minimum detection limit:3 sensitivity reference products L1, L2, L3, the test result should not be lower than L2, L1 is positive, L2 can be positive or Negative, L3 is negative;

◆ Repeatability: precision reference product, which should be positive and consistent in color.

【WARNING AND PRECAUTIONS】

- ◆ Restricted by the methodology of antigen detection reagents, the minimum detection limit is generally lower than that of nucleic acid reagents. Therefore,researchers should pay more attention to the negative results of antigen detection and comprehensive judgment should be combined with other results. It is recommended to conduct nucleic acid testing or virus isolation and culture identification methods for suspicious negative results to assist in judgment
- ◆ Unreasonable collection, transportation, processing, and low virus content in the sample may lead to false negative results.
- ◆ The test results of this reagent are for clinical reference only, and should not be used as the only basis for clinical diagnosis and treatment. The final diagnosis of the disease should be made after comprehensive evaluation of all clinical and laboratory results.
- ◆ This kit is only used for in vitro diagnosis and should not be used for other purposes.
- ◆ The collection, storage and testing of samples should be carried out in strict compliance with the "Technical Guidelines for Laboratory Testing of Pneumonia Infected by Novel Coronavirus (Second Edition)" and "Guidelines for Biosafety of Novel Coronavirus Laboratory (Second Edition)"
- ◆ Operators need to carry out testing operations strictly in accordance with the kit and instrument instruction manual, otherwise it may lead to invalid or wrong results.
- ◆ ProClin300 contained in this kit may cause allergic reactions. Avoid prolonged contact of the reagent with the skin, and wash your hands thoroughly after the reagent is processed.
- ◆ It is forbidden to use any components of the kit with visible damage, or any components with broken seals. If the desiccant is missing from the aluminum foil bag, do not use the test card.
- ◆ Sample collection, storage and testing should be carried out in strict accordance with the "Technical Guidelines for Laboratory Testing of Pneumonia Infected by Novel Coronavirus" and "Guidelines for Biosafety of Novel Coronavirus Laboratory".
- ◆ The storage of the remaining samples after the inspection and the disposal of various wastes should be handled in strict accordance with the "Guidelines for Biosafety of Novel Coronavirus Laboratory" and the "2019 Novel Coronavirus Pneumonia Clinical Laboratory Testing Biosafety Protection Guidelines" for processing: the waste or remaining samples generated during the testing process are recommended to refer to the above guidelines, and first use ether, 75% ethanol, chlorine-containing disinfectant, peracetic acid and chloroform and other lipid solvents to inactivate the virus, and then follow the above guidelines to deal with infectious agents.

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- ◆ **【 Medical device registration certificate number/product technical requirement number】**
- ◆ **【Manual approval and revision date】**