Instructions of New Coronavirus (SARS-CoV-2) N Protein Detection Kit
(Fluorescence Immunochromatography)

【Product name】

New Coronavirus (SARS-CoV-2) N Protein Detection Kit (Fluorescence Immunochromatography)

【Packing specification】

10 Servings/box, 50 Servings/box, 100 Servings/box

【Intended use】

The kit is used for the qualitative detection of new coronavirus nucleocapsid (N) antigen in human throat swab samples in vitro. It is only used as a supplementary detection indicator for suspected cases of new coronavirus negative nucleic acid detection or used in conjunction with nucleic acid detection in the diagnosis of suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonitis infected by new coronavirus, and is not suitable for screenings in the general population.

Coronavirus (Coronavirus, CoV) is a single-stranded positive-stranded RNA virus with membrane. It belongs to Capsuloviruses, Coronaviridae, Coronavirus, and is the largest RNA virus known currently. According to the phylogenetic tree, the coronavirus can be divided into four genera: α, β, γ, and δ. Among them, the β coronavirus can be divided into four independent subgroups A, B, C, and D again. So far, in addition to the new coronavirus that caused an outbreak of viral pneumonia in Wuhan, a total of six coronaviruses (HCoV-229E, HCoV-OC43, SARS-CoV, HCoV-NL63, HCoV-HKU1, and MERS-CoV) which can infect people were found. HCoV-229E and HCoV-NL63 belong to α coronavirus. HCoV-OC43, SARS-CoV, HCoV-HKU1 and MERS-CoV are β coronaviruses. Among them, HCoV-OC43 and HCoV-HKU1 belong to the A subgroup and SARS -CoV belongs to subgroup B, and MERS-CoV belongs to subgroup C [1-3].

【Test principle】

A mouse anti-SARS-CoV-2 N protein antibody was coated on a nitrocellulose membrane as a test line, and a goat anti-rabbit secondary antibody was coated on a nitrocellulose membrane to make a quality control line. Another mouse anti-SARS-CoV-2 N protein monoclonal antibody labeled with latex fluorescent microspheres and rabbit IgG labeled with latex fluorescent microspheres were mixed and sprayed on a glass cellulose membrane to prepare a label pad. One end of the nitrocellulose membrane near the quality control line is covered with a water absorption pad, and the other end near the test line is covered with a marker pad. The sample pending to test is added to the marker pad, and the antigen will react with the marker and carry out chromatography along the nitrocellulose membrane, resulting to react with the test line and quality control line, respectively. When the test result is valid, the quality control line shows a certain light intensity. At this time, the ratio of the optical signal intensity on the test line to the optical signal intensity on the quality control line (T / C) is positively related to the sample concentration.

【Main components】

Each box contains a 10/50/100 person test cards and a desiccant. The main components are as follows:

Compose	Main components & Contents
Detection card	Containing a mouse anti-SARS-CoV-2 N protein antibody and goat anti-rabbit secondary antibody (immobilized on a nitrocellulose membrane), another mouse anti-SARS-CoV-2 N protein monoclonal antibody labeled and rabbit IgG labeled with latex fluorescent microspheres (mixed and sprayed on the marker pad), a water absorbent pad, and a plastic case.

Required items not provided: Hank's solution based preservation solution

【Storage conditions & period of validity】

1. The kit is stored at 10 ℃～30 ℃, and the validity period is tentatively set to 12 months.

2. The components of different batches must not be mixed. Each component is stable under the specified conditions, and can reach the specified validity period on the kit. See the label for the production date and expiry date.

【Sample request】

The sample should be processed by preservation solution of sample as soon as possible after sample collection. It is recommended to detect within 150 min. If the test cannot be performed immediately, the samples should be stored under seal and stored at 2 ℃～8 ℃ for 8 hours. Long-term storage is not recommended.

【Inspection methods】

1. Take out the test card in the environment of temperature 18-28 and humidity 30%-50% (avoid strong convection ventilation environment), cut off the packaging bag and lay it on the table for future use.

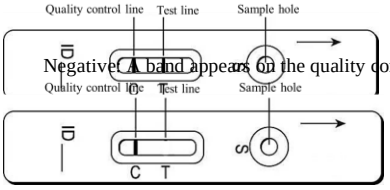
2. Drop 60μL of sample solution to be tested into the sample hole (s) of each test card, leave it at room temperature for 15 minutes, and then check it under ultraviolet irradiation.

【Interpretation of test results】

1. The test results of the kit are only used for clinical auxiliary diagnosis, not the only basis for clinical diagnosis, and should be comprehensively judged in combination with clinical symptoms and other detection indicators.

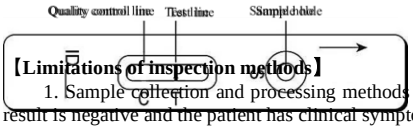
2. When under UV light, the visual inspection results are as follows:

Positive: when a band appears on both the quality control line (C) and the test line (T), it is positive. The test line (T) is considered positive even if a light band appears.



Negative: A band appears on the quality control line (C) and no band appears on the test line (T).

Re-test: If there is no band on the quality control line (C) or the test line (T), or there is only a band on the test line (T), you need to test again.



【Limitations of inspection methods】

1. Sample collection and processing methods have a greater impact on virus detection. Negative test results do not exclude the possibility of virus infection. If the test result is negative and the patient has clinical symptoms, it is recommended to use virus isolation and culture for confirmation, and a comprehensive diagnosis by the attending physician.

2.The collected samples may be contagious, and the processing and testing operations of the samples should be performed in compliance with China's relevant biosafety regulations.

【Product performance index】

1. Appearance: The test card should be neat and unbroken, no burrs, no damage, no pollution; the material should be firmly attached.
2. Film strip width: The width of the film strip should be ≥3 mm.
3. Migration speed: The liquid migration speed should not be less than 10 mm/min.
4. Minimum detection limit: The minimum detection limit is 100 ng/mL.
5. Repeatability: Use repeatable reference products for testing, and the results should all be positive.
6. Negative compliance rate: The negative reference rate (-/-) should be 10/10.
7. Positive compliance rate: The positive reference rate (+ / +) should be 3/3.
8. Cross-reactivity: No significant cross-over with other coronavirus (HCoV-229E, HCoV-OC43, HCoV-NL63, HCoV-HKU1).
9. Interference factors:

(1) No interference reaction with the following drugs: guaiacol glyceryl ether, ribavirin, phenylephedrine, chlortrimeton, levofloxacin, tobramycin, lopinavir, oseltamivir, ritonavir, peramivir, cefradine, zanamivir, flunisolide, fluticasone, dexamethasone, mometasone, beclometasone, triamcinolone, and fluocinolone acetonide 21-acetate.

(2) No interference with mucin samples.

(3) No interference reaction when the blood concentration in the sample is not higher than 2%.

【Announcements】

1. The test must comply with the requirements of laboratory management specifications and strictly prevent cross-contamination. All samples, washes and wastes should be treated as infectious agents.
2. Sample processing: Firstly, 0.5 mL of sample preservation solution is added into the preservation tube. And then, the swab after sample collection is immersed in the sample preservation solution and stirred. Squeeze the outside of the tube with your fingers several times to fully saturate the swab with the sample preservation solution. The wringing liquid is the sample pending to test. The built-in swab directly puts into the preservation tube after collecting samples. The small hole in the cover of the preservation tube is aligned with the top of the tube body, and the tube cover is tightened by rotation.
3. The sample cannot be inactivated（56 ℃ for 30 min, 75% ethanol or otherwise inactivated samples after processing, cannot be used.） and the test is performed under the protection of biological safety. It is recommended that the turbid samples be placed in a centrifuge for 10 minutes, and then the supernatant is used.
4. When collecting samples, be careful not to touch saliva. If touching saliva, resampling is recommended ; If there is strong viscous liquid (snot, sputum) in the collected sample, please resample.
5. The swab head shall be made of cotton.
6. Read the operating instruction carefully before operation, and strictly follow the operation procedures of the instruction. Calibration information cards and test cards of different batches cannot be mixed. Test cards should be stored dry.
7. Add the sample slowly and slowly. After the sample is added, place the test card horizontally on the experimental bench and wait for the chromatographic reaction.
8. The reaction time is 15 minutes, and the error does not exceed 1 minute. The reaction was completed, and the result was invalid after more than 10 minutes.

【Explanation of the Marking】

Marking	Explanation of the Marking	Marking	Explanation of the Marking	Marking	Explanation of the Marking	Marking	Explanation of the Marking	Marking	Explanation of the Marking
IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		CAUTION	LOT	BATCH CODE		MANUFACTURER	EC REP	EC AUTHORIZED REPRESENTATIVE
CE	CE MARK		CONSULT INSTRUCTIONS FOR USE		TEMPERATURE LIMITATION		DO NOT REUSE		USE BY

【References】

[1] Van Der Hoek L, Pyrc K, Jebbink MF, Vermeulen Oost W, Berkhout RJ, Wolthers KC, Wertheim Van Dillen PM, Kaandorp J, Spaargaren J, Berkhout B. Identification of a new human coronavirus[J]. Nature medicine, 2004, 10(4): 368-373.

[2] Hu qian, Tan wenjie. Research progress of human coronavirus HCoV-OC43 [J]. Chinese Journal of Preventive Medicine, 2013, 47(7): 661-664.

[3] Dong xiaochun. Research progress of human coronavirus HCoV-229E [J]. Occupation and Health, 2014, 30(24): 3625-3627, 3631.

【Basic information】

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