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2019-nCoV Antigen Detection Kit (Immunochromatography) Usage Manual

【Product Name】

2019-nCoV Antigen Detection Kit (Immunochromatography)

【Packing Specifications】

20 Tests/Kit, 25 Tests/Kit, 50 Tests/Kit, 100 Tests/Kit.

【Intended Use】

This kit is used for qualitative detection of 2019-nCoV antigen in human pharyngeal and nasal samples.

2019-NCOV is a novel coronavirus, belonging to the genus β..It can cause viral pneumonia, The main clinical manifestations are fever, fatigue and dry cough. A few patients are accompanied by nasal congestion, runny nose, sore throat and diarrhea.Severe cases usually develop dyspnea and/or hypoxemia a week later, with rapid progression to acute respiratory distress syndrome, septic shock, hard-to-correct metabolic acidosis, and haemorrhagic dysfunction in severe cases.

The product adopts cross-flow immunoassay, it used for the qualitative detection of novel Coronavirus antigen in suspected patients nasopharyngeal and oropharyngeal swabs.During the acute phase of infection, antigens are usually detected on nasopharyngeal and oropharyngeal swabs.Positive results indicate the presence of viral antigen, but the clinical relevance of the patient's medical history and other diagnostic information is also necessary to determine the status of infection.A positive result does not rule out bacterial infection or co-infection with other viruses.The detected pathogen may not be the exact cause of the disease.Negative results do not rule out Novel coronavirus infection and should therefore not be used solely as a basis for treatment or patient management decisions, including infection control decisions.Negative results should be considered based on the patient's recent exposure, history, and the presence of clinical signs and symptoms consistent with COVID-19, and if necessary confirmed by nucleic acid analysis .

2019-nCoV Antigen Detection Kit is intended for use by trained clinical laboratory personnel who have been instructed and trained in specialized in in vitro diagnostic procedures.

【Test Principle】

This kit is an immunoassay method based on the principle of double antibody sandwich technique.Novel Coronavirus monoclonal antibody labeled with microspheres was used as the indicator marker and sprayed on the binding pad.During the test, the Novel Coronavirus antigen in the sample was combined with a microblob-labeled Novel Coronavirus monoclonal antibody to form an antigen-antibody complex.The complex migrates up the membrane by capillary effect until it is captured by a precoated monoclonal antibody against another novel coronavirus at the detection line to form a sandwich complex.If a Novel Coronavirus antigen is present in the sample, a red band appears in the t-region of the interpretation window.Otherwise, it is a negative result.The control line (C) is used for program control and should always be displayed if the test program is executed correctly.

【Main Components】

The kit consists of a test card, a sample buffer (drop bottle), a sample extraction tube, and a drop head.

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Test card: it is composed of aluminum foil bag, desiccant, test strip and plastic card.The test strip is composed of absorbent paper, nitrocellulose membrane, sample pad, binding pad and rubber plate.Nitrocellulose membrane T line (test line) is coated with 2019-NCoV antibody, C line (quality control line) is coated with sheep anti-mouse polyclonal antibody, and the binding pad contains latex microspheres labeled 2019-NCoV antibody.

Sample buffer: phosphate, sodium azide, etc.

【Storage and Validity】

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

After the aluminum foil bag is opened, the validity period is 1 hour.

Production date: see label for details.

Expiry date: see label for details.

【Sample Requirements】

A polyester sponge sample with a PP (polypropylene) rod is recommended for sterile sample collection.

(1) The collection method of oropharyngeal sample: the head of the collected person is slightly tilted, the mouth is open, and the pharyngeal tonsils on both sides are exposed.Apply the swab across the base of the tongue to the pharyngeal tonsils on both sides of the recipient for at least 3 times, and then wipe the swab up and down the posterior pharyngeal wall for at least 3 times.

(2) Nasopharyngeal sample collection method: sampling personnel gently support the head of the collected personnel with one hand, with one hand holding the swab, the swab is inserted into the nostril, and slowly penetrate backward along the bottom of the inferior nasal meatus. Because the nasal meatus is curved, excessive force should not be used to avoid traumatic bleeding.When the top of the swab reaches the posterior wall of the nasopharynx, gently rotate the swab once (pause for a moment in case of reflex cough), and then slowly remove the swab.

(3) Sample treatment: Samples collected should be treated with the sample buffer provided by this kit as soon as possible (if not immediately processed, the samples should be stored immediately in a dry, sterilized and tightly sealed plastic tube), and stored at 2℃ to 8℃ for no more than 24h;Long-term storage at -70℃, but repeated freezing and thawing should be avoided.

【Test Method】

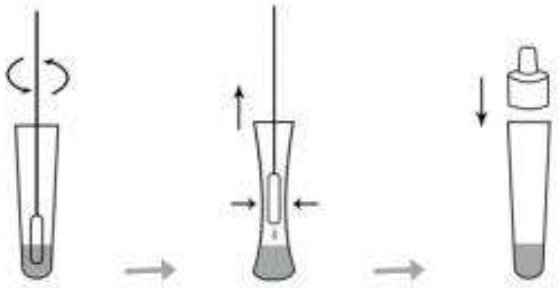
Read the instructions carefully before the test.Restore all reagents to room temperature before testing. The test should be conducted at room temperature.

I. Extraction of specimens (see Figure 1)

1. Add 400μL (about 10 drops) sample buffer vertically to the sample extraction tube, then insert the sampled sample into the solution, rotate close to the inner wall about 10 times, so that the sample can be dissolved in the solution as much as possible.

2. Squash the sample tip along the inner wall of the extraction tube to keep the liquid in the tube as much as possible, remove and discard the sample.

3. Cover the emitter



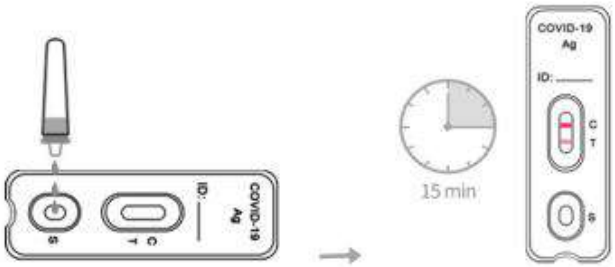
（图 1）

II. Test Procedure (See Figure 2)

1. Remove the test card from the sealed bag.

2. Add 2 drops (about 80μl) of the treated sample extract to the adding well of the test card, and then start the timer.

3. Read the results when the test card is placed at room temperature for 15 minutes.The result was invalid after 20 minutes.



（图 2）

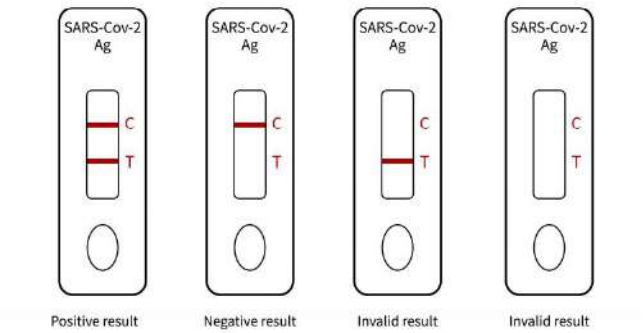
【Interpretation of test results】

Test card result judgment diagram (Figure 3) :

① Invalid results: no reaction line appeared in the quality control line (line C), and the test was invalid. The experiment should be redone.

② Negative results: a red ribbon, quality control line (line C) color.

③ Positive result: two red bands, color display on both test line (T line) and quality control line (C line).



（图 3）

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【Limitations of the test method】

1. This kit is for qualitative detection and is only used for in vitro auxiliary diagnosis.

2. Restricted by antigen detection reagent methods, The limit of detection (sensitivity analysis) is generally lower than that of nucleic acid reagents, so researchers should pay more attention to the negative results of antigen detection and make comprehensive judgments in combination with other test results.

3. False negatives may be caused by improper sampling, transportation, handling and low virus content in the sample.

4. The test results of this reagent are only for clinical reference and should not be used as the sole basis for clinical diagnosis and treatment. The final diagnosis of the disease should be made after a comprehensive evaluation of all clinical and laboratory results.

【Product Performance Index】

1. The limit of detection: The inactivated SARS-CoV-2 virus culture was used in this study, and the minimum detection limit of the kit was 6×102TCID50/mL.

2. Use the enterprise reference materials for testing, and the results should meet the requirements of the enterprise reference materials.

2.1 Conformance rate of positive reference: positive reference P1-P5 of the enterprise shall be tested, and the results shall all be positive.

2.2 Conformance rate of negative reference: Negative reference N1-N10 of the enterprise shall be tested, and the results shall all be negative.

2.3 The limit of detection:Test with the LOD references L1 should be negative, L2 and L3 should be positive.

2.4 Repeatability:Test with the repetitive references. Results of J1 and J2 shall be positive for 10 times respectively

3. Cross-reaction:This product with the coronavirus (HKU1 OC43, NL63 and 229 e), influenza A H1N1 (new influenza A (H1N1) virus (2009), the seasonal H1N1) and H3N2, H5N1, H7N9, hib (department of Yamagata, Victoria), respiratory syncytial virus and rhinovirus group A, B, C, adenovirus, 1, 2, 3, 4, 5, 7, 55, enterovirus group A, B, C, D,There was no cross-reaction in the positive samples of Epstein-Barr virus, measles virus, human cytomegalovirus, rotavirus, norovirus, mumps virus, varicella-zoster virus and mycoplasma pneumoniae antigen.

No cross-reaction was observed with the following bacteria at 1.0×106 CFU /mL: Legionella pneumophila, Haemophilus influenzae, Streptococcus pyogenes (group A), Streptococcus pneumoniae, Escherichia coli, Pseudomonas aeruginosa, Neisseria meningitidis, Candida albicans, Staphylococcus aureus.

4. Interferents:The kit evaluates potential interferences at the concentrations listed below and finds that they do not affect test performance.

Mucin 1mg/mL, whole blood 1%, hydroxymetazoline 10mg/mL, histamine hydrochloride 10mg/mL, tobramycin 1mg/mL, oseltamivir 1mg/mL, zanamivir 1mg/mL, abidol 0.5mg/mL, ribavirin 0.4mg /mL, fluticasone 0.5mg/mL, dexamethasone 5mg/mL, triamcinolone acetonide 5mg/mL, levofloxacin 0.2mg /mL, azithromycin 0.1mg/mL, ceftriaxone 0.4mg/mL, meropenem 0.2mg/mL.

5. Hook effect:No hook effect was observed when Novel coronavirus culture was inactivated at a high concentration of 1.0×106 TcuD 50/mL.

6. Clinical study: 288 swabs were collected from suspected COVID-19 patients within 7 days after symptom onset, compared with RT-PCR detection reagent as a contrast reagent. The test data were

summarized as follows:

Resgenzien		zhongxiu		Total
		Positive	Negative	
RT-PCR	Positive	65	6	71
	Negative	2	215	217
Total		67	221	288
Positive coincidence rate:(PPA)		91.55% (65/71), (95%CI: 82.76%～96.07%)		
Negative coincidence rate:(NPA)		99.08% (215/217), (95%CI: 96.70%～99.75%)		

【Precautions】

1. Only used for in vitro diagnosis.
2. This product is disposable and cannot be recycled and reused after using.
3. Please read the instructions carefully before operation, and strictly follow the instruction.
4. Do not conduct experiments in harsh environments (such as containing 84 disinfectant, sodium hypochlorite, acid-base or ethanol and other high-concentration corrosive gases and dust) conditions. Laboratory disinfection should be performed after the experiment.
5. All samples and reagents should be treated as potentially infectious substances, and shall be disposed in accordance with "The Principles of Waste Disposal in Clinical Laboratories" and "The Management Ordinance of Medical Waste".
6. Please use the reagents within the validity period of the package label. The test card should be used as soon as possible after it is removed from the foil bag to prevent moisture

【Index of Symbols】

	Do not re-use	30℃ 2℃	Store at 2℃～30℃
	Consult instructions for use	IVD	In vitro diagnostic medical devic
LOT	Batch code		Use-by date
	Keep dry		Keep away from sunlight
EC REP	Authorized representative in the European Community		Manufacturer

【Basic Information】

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