Novel Coronavirus (COVID-19) Antigen Detection Kit

(Latex Immunochromatography)

Instruction for Use

【Product name】

Novel Coronavirus (COVID-19) Antigen Detection Kit (Latex Immunochromatography)

【Packing specification】

10 tests/box, 25 tests/box, 50 tests/box.

【Intended use】

This product is used to qualitatively detect the novel coronavirus (COVID-19) antigen in human nasopharyngeal swabs, oropharyngeal swabs and saliva samples.

【Test principle】

This kit uses latex immunochromatography and double antibody sandwich immunoassay to detect the novel coronavirus (COVID-19) antigen in human nasopharyngeal swabs, oropharyngeal swabs and saliva samples. Add the sample to the sample well of the test card. Under the action of chromatography, the new coronavirus (COVID-19) antigen in the sample is combined with the new coronavirus (COVID-19) antibody labeled with latex microspheres on the binding pad. A reaction complex is formed, which moves forward along the nitrocellulose membrane and is captured by the novel coronavirus (COVID-19) antibody immobilized on the nitrocellulose membrane detection line (T), the detection line (T) shows Red. If there is no new coronavirus (COVID-19) antigen in the sample, no binding will occur, that is, no red color will appear. Regardless of whether the test substance is present in the sample, the quality control line (C) should be displayed in red, otherwise, the test is invalid.

【Main components】

1. The main components of the test card: the test card is composed of a test strip shell and a test strip.
2. The main components on the test strip are:

a. Binding pad: contains novel coronavirus (COVID-19) antibody labeled with latex microspheres;

b. Nitrocellulose membrane: novel coronavirus (COVID-19) antibody is fixed in the detection area, and goat anti-mouse IgG antibody is fixed in the quality control area;

c. Sample pad, absorbent paper, PVC bottom plate.

Number	Name	10 Tests/Kit	25 Tests/Kit	50 Tests/Kit
1	Test card（1 Test）	10	25	50
2	Instruction for use	1	1	1
3	Sample extraction tube and dripper	10 sets	25 sets	50 sets

4	Sample extraction buffer	1 bottle	2 bottles	2 bottles
5	Nasopharyngeal swab	10	25	50
6	Saliva collection tube and funnel	10 sets	25 sets	50 sets

【Storage conditions & period of validity】

1. The kit is stored at 2℃~30℃, and the validity period is 18 months.
2. When the humidity is below 60%, use within 1 hour after opening the aluminum foil bag; when the humidity is above 60%, use it immediately after opening the aluminum foil bag.
3. Avoid heavy pressure, moisture, and heat during storage.

【Sample requirement】

The sterile swab head for sample collection is recommended to use polyester fiber material, and the swab rod should use a wooden or plastic handle.

1. Collection of nasal secretions: when collecting nasal secretions, insert the swab into the place where the secretions are the most in the nasal cavity, gently turn and push the swab into the nasal cavity until the turbinate is blocked (about 2.0 cm ~ 2.5 cm from the nostril). Rotate the swab three times against the wall of the nasal cavity and remove the swab.
2. Collection of throat secretions: Insert the swab completely from the mouth into the throat, centering on the redness of the throat wall and the upper palate tonsils, wipe the bilateral pharyngeal tonsils and posterior pharyngeal wall with moderate force, avoid touching the tongue, and remove the swab.
3. Before collecting saliva, relax your cheeks and gently massage your cheeks with your fingers for 15-30 seconds to produce saliva. Spit the saliva gently into the funnel until the liquid saliva (without bubbles) reaches the height of the 2.0 ml mark.
4. The virus sampling solution or the sample extraction solution provided in this kit should be used for processing as soon as possible after sample collection. If it cannot be processed immediately, the sample should be stored immediately in a dry, sterilized and strictly sealed plastic tube. It can be stored at 2℃~8℃ for 8 hours, and at -20℃ it can be stored for a long time.

【Test methods】

Please read the instruction carefully before use. Samples, reagents and other required equipment should be used after returning to room temperature. If you open the package, you should use it as soon as possible within 1 hour.

1. Specimen extraction (see Figure 1)

(1). Vertically add 350μL (approximately 7-8 drops) of sample extraction solution into the sample extraction tube or saliva collection tube..

(2). Insert the swab after sampling into the solution in the sample extraction tube, and squeeze the swab in the tube about 6 times to make the sample dissolve in the solution as much as possible.

(3). Squeeze the head of the swab along the inner wall of the tube to keep the liquid in the tube as much as possible, remove and discard the swab.

(4). Cover the dripper.

2. Testing procedures (see Figure 2)

1. Open the aluminum foil bag along the tear opening, take out the test card, and lay it flat.
2. Add 80μL (about 1~2 drops) of the processed sample extract to the sample hole of the test card or directly add 80 μ L of the processed virus sampling solution.
3. Observe the displayed results within 15-20 minutes, and the results displayed after 30 minutes have no clinical significance.

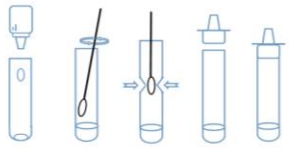

Figure 1

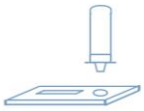

Figure 2

【Interpretation of test results】 (see Figure 3)

Positive: There are clear red bands on the test line (T) and quality control line (C), and it is judged that the novel coronavirus (COVID-19) antigen test is positive;

Negative: Only a clear red band appears at the position of the quality control line (C), and it is judged that the novel coronavirus (COVID-19) antigen test is negative;

Invalid: There is no red band at the position of the quality control line (C), and the test is invalid regardless of whether there is a red band at the position of the detection line (T).

Note: The color depth of the reaction line is related to the content of the tested substance contained in the extracted sample. Regardless of the color intensity, the result should be determined according to whether the reaction line is colored.

This reagent contains a quality control process. When a red reaction line appears in the C area, it indicates that the operation is correct and effective, otherwise the test is invalid.

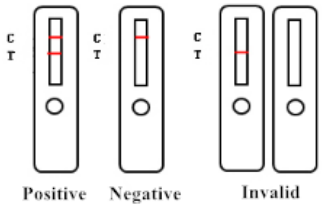

Figure 3

【Limitations of inspection methods】

1. This reagent is only for detecting respiratory secretions and saliva samples.

2. The accuracy of the test depends on the sample collection process. Improper sample collection, improper sample storage, stale sample or repeated freezing and thawing of samples will affect the test results.

3. The test card only provides qualitative detection of the COVID-19 antigen in the sample. If you need to test the specific content of a certain index, please use relevant professional instruments.

4 The test results of this reagent are for clinical reference and are not used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in conjunction with their symptoms/signs, medical history, other laboratory tests and treatment responses.

5. Due to the methodological limitations of antigen-based test reagents, its analytical sensitivity is generally lower than that of nucleic acid-based reagents. Therefore, experimenters should pay more attention to negative results and need to combine other test results for comprehensive diagnosis. It is recommended that negative results in doubt use nucleic acid testing for review.

6. Analysis of the possibility of false negative results:

①Unreasonable sample collection, operation and processing, and low virus titers in the sample may lead to false negative results.

②Various gene mutations may cause changes in antigenic determinants, resulting in false negative results. This type of situation is more likely to occur with monoclonal antibody reagents.

③The optimal sample type and the optimal sampling time after infection (peak virus titer) have not been verified. Therefore, collecting samples from multiple sites in the same patient may avoid false negatives.

【Product performance index】

1. Positive coincidence rate: 5 copies of the novel coronavirus (COVID-19) recombinant antigen reference material (P1~P5) are tested, and the results should all be positive.
2. Negative coincidence rate: 5 copies of novel coronavirus (COVID-19) recombinant antigen reference materials (N1~N5) are tested, and the results should all be negative.
3. Minimum detection limit: 3 copies of the novel coronavirus (COVID-19) recombinant antigen reference material (L1~L3) should be tested. L1 should be negative, L2 and L3 should be positive.
4. Repeatability: Repeat the detection of the novel coronavirus (COVID-19) recombinant antigen reference (R) 10 times, and the results should all be positive.

【Precautions】

1. The kit is for in vitro diagnostic use only.
2. The test card, sample extraction tube and dripper are all disposable and cannot be reused.
3. Please check the integrity and expiry date of the kit packaging before use, and then open the package. When storing at low temperature, it should be restored to room temperature before opening the package for use. Reagents whose single package is damaged and expired cannot be used.
4. The components in the kits of different batch numbers cannot be exchanged.
5. After the test card is taken out of the aluminum foil bag, the experiment should be carried out as soon as possible to avoid leaving it in the air for too long, which may cause moisture.
6. Pay attention to safety measures during operation, such as wearing protective clothing and gloves.
7. The detection temperature is 15℃ ~ 30℃, and the relative humidity is 40% ~ 60%.
8. There is a desiccant in the aluminum foil bag and it is not allowed to be taken orally.
9. There is no ribbon on the quality control line and the inspection line, indicating that an error detection has occurred and the inspection should be repeated.
10. All specimens, reagents and potential contaminants should be disinfected and processed in accordance with relevant local regulations

【Approval Date and Revision Date of the Instruction for use】

Approval Date: July 15, 2020
Revision Date: NA
Date of Issue:

【Index of CE Symbols】

	The product is used in vitro, please don't swallow it.		Please don't reuse it
	Validity		Please read the instruction book carefully before using
	Warning, please refer to the instruction in the annex		Manufacturer
	Temperature scope within which the product is reserved		Batch number
	European union authorization representative		Keep dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged

	Date of manufacture		Biological risks
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		Tests per kit

Zhejiang GENE SCIENCE Co., Ltd
Address: No. 2 workshop, pharmaceutical industrial park, no. 11 shengxing road, shangyu economic and technological development zone, hangzhou bay, zhejiang province.
Tel: 0575-82963126
Post code：312300

Lotus NL B. V.
Address: Koningin Julianaplein 10, l e Verd, 2595AA, The Hague, Netherlands.
E-mail: Peter@lotusnl.com

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