SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)

Instructions For Professional Use

For human oropharyngeal or anterior nasal, saliva samples

[Product Name]

SARS-CoV-2 Antigen Detection Kit (Latex Lateral Flow Assay)

[Packing Specifications]

1 Test/box、2 Test/box、5 Test/box、25 Test/box

[Intended Use]

This kit is used for in vitro qualitative detection of coronavirus (Covid-19) in human oropharyngeal or anterior nasal, saliva samples.。

This kit is only suitable for the preliminary screening of novel coronavirus assay.The test kit can detects the N protein,cannot detect the S protein and its mutation structure.. If further confirmation or further accurate concentration of the sample is required, must do more sensitive detection, such as nucleic acid detection.

[Detection Principle]

Coronavirus (Covid-19) is a kind of acute respiratory tract infectious disease, the person is very easy and universal infection, according to current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days.The main manifestations are fever, fatigue, dry cough, a few cases may appear anterior nasal congestion, runny nose, sore throat, myalgia and diarrhea. The coronavirus (Covid-19) antigen detection can directly detect the Coronavirus, accurate, low requirement to the equipment and personnel, is a one-step sandwich immunoassay, using two kinds of antigen specific antibody to identify and in combination with a target antigen different table, can greatly reduce the risk of cross reaction, thus effectively improve its specificity. With lower cost and shorter response time, antigen assay is suitable for a wide range of novel coronavirus assays.

The coronavirus protein N can be used as an immunogen to stimulate plasma cells to produce specific antibodies after virus infection. According to the double-antibody sandwich principle, the sample is dropped onto the sample pad, and then through the liquid chromatography, the detection line (T line) and the quality control line (C line) on the NC membrane are successively passed through the latex pad. The latex pad contains labeled antigen-specific antibodies that bind to the antigens (viral proteins) in the sample. When the fluid flow reaches the test line (T line), a second antigen-specific antibody fixed at this line binds to the antigen again and produces a positive result. When the liquid flow reaches the quality control line (line C), the antibody in the latex pad binds to the coated sheep anti-mouse IgG antibody and presents the C quality control line.

[Main components]

Number of components Main components

components	Number	Main components
Card	1/2/5/25tests	Each test card consisted of a nitrocellulose membrane (NC membrane) coated with Coronavirus monoclonal antibody and a sheep anti-mouse IgG antibody, and a latex pad coated with another Coronavirus monoclonal antibody.
extraction tube	1/2/5/25pcs	contain diluent of 0.5mL
swab	1/2/5/25pcs	/
paper bag	1/2/5/25pcs	/
Quantitative dropper	1/2/5/25pcs	/
instructions	1/1/1/1pcs	/

[Storage Conditions and Validity]

1. Storage conditions: the original package should be stored at 2~30℃, forbidden to freeze.

2. Validity period: 12 months.

3.The reagent should be used up within 1 hour after the aluminum foil bag is unsealed to prevent its failure in the air. It should be used out of the box as far as possible.

4. See label for production date and expiration date.

[Sample Collection and Pre-treatment]

Oropharyngeal swab collection method:

1. Tilt the patient's head slightly;

2. Instruct the patient to open his mouth as wide as possible to expose the pharyngeal tonsils on both sides;

3. Wipe the patient's tongue base with a cotton swab;

4. Gently rub the pharyngeal tonsils back and forth at least 3 times on both sides of the swab;

5. Rub the throat wall up and down at least 3 times;

6.Dip the swab head into the virus lysis solution, hold the sample tube by hand and knead the swab head to dissolve the sample in the liquid as much as possible, discard the tail of the swab, cover the tube tightly and shake for 5 seconds to test the sample as soon as possible.

anterior nasal swab collection method:

1.Please raise the patient's head slightly and remove the secretions on the surface of the anterior anterior nasal foramen;

2. Gently and slowly insert the swab to the anterior nasal cavity;

3. Gently wipe the anterior nasal wall secretions with a anterior nasal swab and remove the swab;

4. Dip the swab head into the virus lysis solution, hold the sample tube by hand and knead the swab head to dissolve the sample in the liquid as much as possible, discard the tail of the swab, cover the tube tightly and shake for 5 seconds to test the sample as soon as possible.

Saliva collection method:

1. Patients should clean their mouth 30 minutes before saliva collection, and avoid eating, smoking or chewing gum;

2. Instruct the patient to gently spit into the paper bag (about 3-4 times) until the volume of saliva reaches 1/5 of the volume of the paper bag, and avoid blistering as much as possible during the process. If the amount of saliva is too little, the patient can be instructed to increase the secretion of saliva by pressing the tongue against the palate or the jaw;

3. The paper bag with collected saliva should be placed at room temperature for 20 minutes to burst the foam, to avoid the problem of inaccurate sampling amount caused by the absorption of foam.

4. Take an extraction tube, unscrew the cover of the extraction tube, use the quantitative dropper to suck 80ul saliva from the paper bag (fill one tube) into the extraction tube, mix well, close the cover of the tube, shake for 5 seconds, and test the sample as soon as possible;

[Test Method]

1. You must read the instructions thoroughly before test;

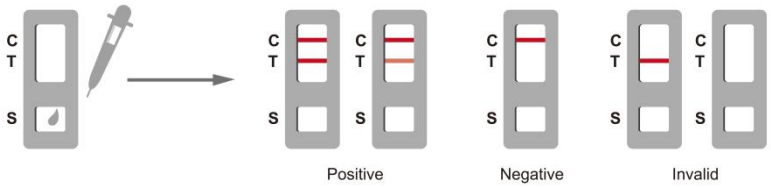
2. Tear open the packaging bag, take out the test card, place the test card on the horizontal table for testing, and use it up within 1 hour;

3.Put the sample tube (containing the sample) upside down and drop about 50ul (2 drops) of sample into the sample well;

4. The results were interpreted 15 minutes after adding samples, and the observation results after 20 minutes were invalid.

Note: The experiment should be carried out at a temperature of 20-25℃.

[Interpretation of Test Results]



1. Positive (+) : Two red bands appear, one in the quality control area (C) and the other in the test area (T)

2. Negative (-) : only one purple band appears in the quality control area (C), and no purple band appears in the test area (T)

3. Invalid: Colorless band appears in the quality control area, or only purplish red band appears in the test area (T).It should be retested.

[Limitations of the test method]

1. This kit belongs to chromatography kit, and is only used for in vitro auxiliary diagnosis;

2. False negatives may result from improper sampling, transportation, handling and low virus content in samples;

3. For doubtful test results, the researcher should combine the patient's symptoms and perform further tests, such as nucleic acid tests, to assist in judgment;

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.

[Product performance indicators]

In this clinical trial,380 clinical case samples which include 120 confirmed as COVID-19 positive and 260 confirmed as COVID-19 negative by PCR assay, were obtained for testing, and then compared the test results between Novel Coronavirus 2019-NCOV Nucleic Acid Detection kit (fluorescence PCR method) and the PCR results. All samples were collected from people with Covid-19 symptoms within seven days of symptoms appearing. Performance characteristics of the test were assessed with anterior nasal, oropharyngeal,saliva samples, and confirmed by an RT-PCR from PCR nasopharyngeal samples.And the sensitivity as below:

1）The results of anterior nasal samples：Sensitivity is 95,833%(95% credibility interval:90,06%，98,46%). Specificity of 99,23% (95% confidence interval: 96,95%-99,87%).

Evaluation reagent	Contrast reagent		Total
	Positive	Negative	
Positive	115	2	117
Negative	5	258	263
Total	120	260	380

2) The results of oropharyngeal samples： Sensitivity is 95%(95% credibility interval:88,98%， 97,9%). Specificity of 99,23% (95% confidence interval: 96,95%-99,87%).

Evaluation reagent	Contrast reagent		Total
	Positive	Negative	
Positive	114	2	116

Negative	6	258	264
Total	120	260	380

3) The results of saliva samples：Sensitivity of 94,17%(95% credibility interval 87,72%，97,42%). Specificity of 99,62% (95% confidence interval: 97,54%-99,98%).

Evaluation reagent	Contrast reagent		Total
	Positive	Negative	
Positive	113	1	114
Negative	7	259	266
Total	120	260	380

[Result of cross reactions and Interference research]

This kit is used with parainfluenza virus samples,influenza A virus,Influenza B virus,Chlamydia pneumonia, Mycoplasma pneumoniae,respiratory syncytial virus,human immunodeficiency virus,Barr virus,measles virus, cytomegalovirus,enterovirus 71,mumps virus,human coronavirus 229E,human coronavirus-OC43,human coronavirus-NL63, and human coronavirus-HKU1 antibody positive samples do not cross.

The drugs levofloxacin, azithromycin, ceftriaxone, meropenem, histamine hydrochloride, interferon, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, abiddo and tobramycin had no effect on the test results.

[Precautions]

1. This product is for screening use only.

2. Please ensure that appropriate amount of specimens are used for testing. Excessive or too small amount of specimens may lead to deviation of results.

3. As this product is visually read, in order to ensure the correct interpretation of the results, do not read the results in the dim light.

4. The reagent should be used up within 1 hour after the aluminum foil bag is unsealed, and it should be used immediately as far as possible.

5. In the interpretation, no matter the depth of the ribbon, as long as the red line appears in the quality control area and the test area, it can be determined as positive.

[Symbol on the Labeling]

Symbol	Meaning	Symbol	Meaning	Symbol	Meaning
CE	Conformite Europeenne		Use-by Date	2℃ 30℃	Temperature limit
IVD	Invitro diagnostic use		For single use only	LOT	Batch Code
	Manufacturer		Consult Instructions for Use	EC REP	Authorized Representative
	Caution				

[Contact Info.]

Shenzhen Aivd Biotechnology Co., LTD.

Address:C501, Building B5, China Merchants Bright Technology Park, Fenghuang Community Sightseeing Road, Fenghuang Street, Guangming District, Shenzhen, Guangdong Province, China

Tel: 0755-2740 4996 E-mail：sales@aivdbiotech.com

EC REP Osmunda Medical Technology Service GmbH Address: Treskowallee 108, 10318 Berlin, Germany

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