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

Instructions

For Professional Use

Product Name:

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

Packing Specifications:

25 test /box

Intended Use:

This kit is used for in vitro qualitative detection of coronavirus (Covid-19) in human pharyngeal or nasal secretions samples.

This kit is only suitable for the preliminary screening of novel coronavirus assay. 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 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：

Components	Number	Description
Test Card	25 tests	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.
Virus lysate diluent	1 bottle	Diluent, 15mL.
The sample tube	25 pieces	
Dropper	25 pieces	
Pharynx/nose swab	25 pieces	

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

Pharyngeal swab collection method:

1. Use the dropper to take 500uL (calibrated) of viral lysate diluent into a sample tube.

2. Tilt the patient's head slightly;

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

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

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

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

7. 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.

Nasal swab collection method:

1. Use the dropper to take 500uL (calibrated) of viral lysate diluent into a sample tube.

2.Please keep the patient's head still and remove the secretions on the surface of the anterior nasal foramen;

3. Gently and slowly insert the swab through the nasal cavity to the nasopharynx;

4. When it encounters resistance, it reaches the posterior nasopharynx and stays for a few seconds to absorb secretions;

5. Gently rotate the swab for removal;

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.

Test Method:

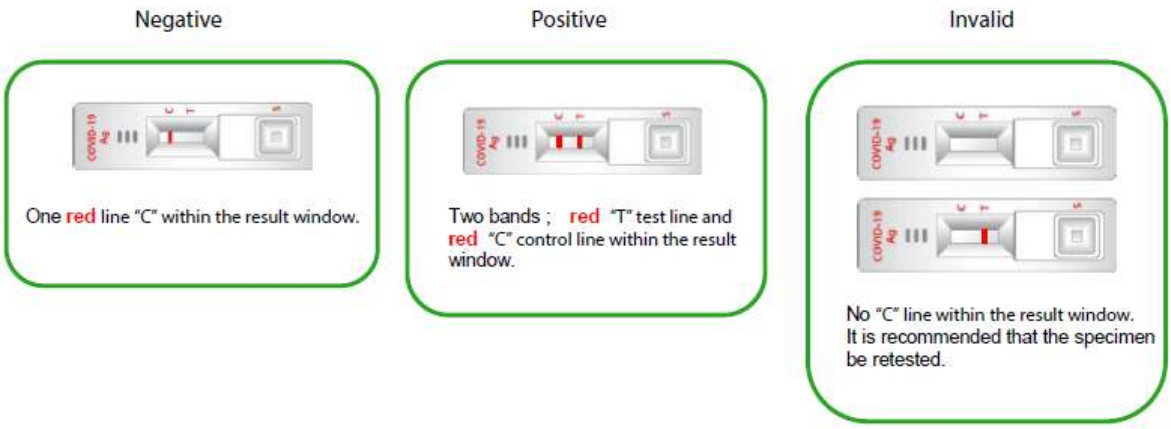
1. Read the instructions thoroughly before test;

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 Characteristics

The coronavirus (Covid-19) antigen detection kit was used to detect 60 positive cases with a sensitivity of 93% (95% confidence interval: 83.52-96.63%).Of 170 negative specimens tested with the Covid-19 antigen detection kit, 168 were negative, with a specificity of 98.82% (95% confidence interval 95.46%-99.47%).

Precautions

1. This product is for screening use only.

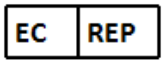
2. Please ensure that appropriate amount of specimens are used for testing. Excessive or too small amount of specimens may lead to deviation of results.

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

	Conformite Europeenne
	in vitro diagnostic use
	Batch Code
	Manufacturer
	Temperature limit
	Use-by Date
	Consult Instructions for Use
	Authorized Representative
	For single use only
	Caution

CMC Medical Devices& Drugs S.L.

C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain