MaxLINE Covid -19 Antigen Test

INTENDED USE: MaxLINE COVID-l9 Antigen Rapid test is used for in vitro qualitative detection of the antigen of novel Corona virus in human throat Swabs or nasal swabs.

SUMMARY AND EXPLANATION OF THE TEST:
The novel Corona viruses belong to the B genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel Corona virus are the main source of infection; asymptomatic infected people can also be an infectious source Based on the current epidemiological investigation; the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

TEST PRINCIPLE
MaxLINE kit based on the lateral flow immunochromatographic technique. The specimen will move forward along the test card under capillary action. If the specimen contains a novel Corona viruses antigen, will bind to the colloidal gold-labeled monoclonal antibody against COVID-19 Nucleocapsid protein. The immune complex will be membrane fixed with monoclonal antibody capture for COVID-19 Nucleocapsid protein; form the fuchsia line, display will be Corona virus antigen positive; If the line does not show color, the negative result will be displayed. The test card also contains a quality control line C, which shall appear fuchsia regardless of whether there is a detection line.

REAGENT AND MATERIAL:

Reagents and Materials Provided
- Antigen extraction tube
- Antigen extraction buffer
- Test card
- Sterile Nasal Swab
- instructions for use

Material Required But Not Provided
1) Pipette Set; 2) Timer

WARNING AND PRECAUTION
1. This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
2. The specimen shall be tested in a laboratory with certain conditions. All specimens and materials during testing should be handled in q accordance with the laboratory practice for infectious diseases.
3. Do not open the sealed pouch unless ready to conduct the assay. Once opened, the cassettes should be used within 2 hours.
4. Do not use expired devices.
5. Bring all reagents to room temperature (15'C-30.C) before use.
6. Do not use the components in any other type of test kit as a substitute or the components in this kit.
7. Wear protective clothing and disposable gloves while handling the kit Reagents and clinical specimens. Wash hands thoroughly after performing the test.
8. Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9. Dispose of all specimens and materials used to perform the test as biohazardus waste.
10. Handle the Negative and Positive Control in the same manner as patient specimens.
11 The testing results should be read between 15 and 20 minutes after a specimen is applied to the sample well. Results read after 20 minutes may give erroneous results.
12. Do not perform the test in a room with strong air flow, i.e. an electric fan or strong air-conditioning.
13. The test methods and results must be interpreted in strict accordance with this specification.
14. Negative results will occur with this kit if the novel corona virus antigen titer in the specimen falls below the minimum detection limit for this kit.

STORAGE AND STABILITY

1. Store the product at 2-30"C.The product is stable up to 24 months.
2. After the aluminum foil bag is unsealed, the test card should be used as soon as possible within one hour.

SPECIMEN COLLECTION AND PREPARATION

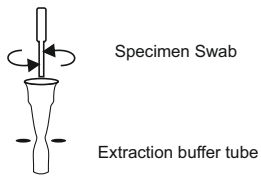
1. Throat swab:
Let the patient's head tilt slightly, mouth open, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with a little hard back and forth at least 3 times. ; Place the swab specimen in the extraction tube with the extraction solution added in advance, rotate the swab for about 10 seconds, and press the swab head against the wall to release the antigen in the swab.

2. Nasal swab:
Let the patient's head relax naturally, and slowly rotate the swab against the wall of the nostril into the patients nostril to the nasal palate, and then slowly remove it while wiping. Using the same swab, wipe the other nostril in the way; place the swab specimen in the extraction tube with the extraction solution added in advance, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the swab antigen.

3. Nasopharyngeal swabs:
Place the nasal swab into the sampling tube where the pharyngeal swab has been collected. In this way, there is a pharyngeal swab and a nasal swab in a sampling tube, so- called nasopharyngeal swab tube. Place the swab specimen in the extraction tube, rotate the swab for about 10 seconds, and press the swab head against the tube wall to release the antigen in the swab.

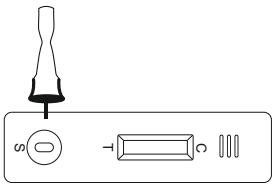
TEST PROCEDURE
The test method was colloidal gold. Please read the manual and the instrument operation manual carefully before use.

1. Open the package and take out the test card.
2. Place the extraction tube on the workbench. The swab Antigen extraction buffer bottle is pressed vertically downward to allow the solution to drip freely into the extractor tube without touching the edge of the tube. Add 10 drops of Antigen extracted buffer to the extractor tube.
3. Put the specimen swab into the extraction tube, rotate the swab for about '10 seconds, and squeeze the swab head against the tube wall of the extraction tube to release the antigen in the buffer to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal method.
4. Install the Nozzle cap on the extraction tube, put 2-3 drops Mucous free extracted sample into the specimen hole of the test card, and start the timer.
5. Read the results within 20 minutes. Positive results can be reported before 20 minutes, the results after 20 minutes are not valid.



insert the swap into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.

Remove the swab while squeezing the sides of the tube to extract the liquid from the swab



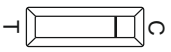
Apply 2-3 drops of extracted specimen to the specimen well of the test device.

Press the nozzle cap tightly onto the tube.

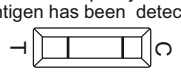
15-20 Minutes

Read the test results in 15-20 minutes.

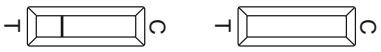
INTERPRETATION OF ASSSAY RESULT
1. **NEGATIVE RESULT:** if there is only a quality control line, the detection line is colorless, indicating that novel Corona virus antigen has not been detected and the result is negative.



2. **POSITIVE RESULT:** if both the quality control line C and the detection line appear, novel Corona virus antigen has been detected and the result is positive for antigen.



3. **INVALID:** if the quality control line C is not observed, it will be invalid regardless of whether there is detection line (as shown in the figure below), and the test shall be conducted again.



LIMITATIONS OF THE PROCEDURE
1. This reagent is only used for in vitro diagnosis.
2. This reagent is only used to detect human nasopharyngeal swab extracts. The results of other specimens may be wrong.,
3. This reagent is only used for qualitative detection and cannot indicate the level of novel Corona virus antigen in the specimen.
4. This reagent is only a clinical auxiliary diagnostic tool. Lf the result is positive, it is recommended to use other methods for further examination in time and the doctor's diagnosis shall prevail.
5. Failure to follow the test procedure and interpretation of test results may be adversely affect test performance and produce invalid result.
6. A negative result may occur if the level of extracted antigen in a specimen is below the sensitivity of the test or if a poor quality specimen is obtained.
7. A negative result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test or if the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility of COVID-19 infection and should be confirmed by viral culture or an molecular assay or ELISA.
8. Positive result, do not rule out co infections with other pathogen.
9. For more accuracy of immune status additional follow up

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