COVID-19 Antigen Self Test
Short Nasal Swab and Saliva Test CE Marked

This corona rapid test is suitable for the qualitative detection of novel coronavirus in nasal swab and sputum samples. You can easily administer this test yourself by using a short nasal swab or by collecting deeply coughed up sputum (saliva) in a paper cup. The sample is mixed with an extraction liquid and then placed on the test cassette, you will have the test result within 15 to 30 minutes.

This product is suitable as a self-test and has been released as such by the FAMHP

If you want to be able to choose to test with a nasal swab or with saliva, this test is the best alternative for you. The test has a sensitivity compared to the gold standard RT-PCR test of 97.3% and a specificity of 99.0%. The total accuracy is 98.1%

Characteristics
SUMMARY

The new coronaviruses belong to the genus. COVID-19 is an acute infectious disease of the respiratory tract. Humans are generally susceptible. Currently, patients infected with the new coronavirus are the main source of infection; asymptomatic virus carriers can also be sources of infection. Based on current epidemiological research, the incubation period is 1 to 14 days, usually 3 to 7 days. The main symptoms are fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and

diarrhea also occur in some cases.

PRINCE

This product is an immunochromatographic membrane test that uses highly sensitive monoclonal antibodies to detect the nucleocapsid protein of SARS-CoV-2. The test strip consists of the following parts: a sample pad, a reagent pad, a reaction membrane and an absorbent pad. The reagent pad contains colloidal gold conjugated to the monoclonal antibody to the SARS-CoV-2 nucleocapsid protein; the reaction membrane contains the secondary antibodies against the SARS-CoV-2 nucleocapsid protein. The whole strip is fixed in a plastic device. When the sample is added into the sample well, the conjugates absorbed into the reagent pad are dissolved and migrate with the sample. If SARS-CoV-2 antigen is present in the sample, the complex of the anti-SARS-CoV-2 conjugate and the virus is captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line (T) . Absence of the T-line indicates a negative result. To verify the procedure, a red line always appears in the control area (C), indicating that the correct volume of sample material has been added and that the membrane drain effect has occurred.

COMPOUND

Test cassette
Sample extraction tube
drip cap
paper cup
Sputumpipet

STORAGE AND STABILITY

Store the product package at a temperature of 2-30 ° C or 38-86 ° F, and avoid exposure to sunlight. The kit is stable within the expiration date printed on the label.
Once the foil pouch has been opened, the test cassette should be used within one hour. Prolonged exposure to a hot and humid environment may cause inaccurate results.
The lot number and expiration date are printed on the label.

WARNINGS AND PRECAUTIONS

Read the instruction manual carefully before using this product.
This product is for professional use ONLY.
This product is suitable for sputum samples. Using other types of samples may cause inaccurate or invalid test results.
Sputum comes from the respiratory tract. This method of sampling is recommended by the WHO.
Make sure the correct amount of sample is added for testing. Too large or too small a

sample can cause inaccurate results
If the test line or control line is outside the test window, do not use the test cassette. The test result is invalid and retest the sample with a new test cassette.
This product is for single use. DO NOT recycle used parts.
Dispose of used products, samples and other consumables as medical waste in accordance with applicable regulations.

MONSTERAFNAME

Have the patient take a deep breath and spit deeply coughed up sputum into the paper cup or sputum container. Note: If the patient has eaten or drunk just prior to sampling, rinse mouth with clean water.

Use the pipette to transfer 0.6 ml of the sputum sample into the extraction tube. The pipette draws up 0.3 ml of sample at a time. Perform the sample transfer procedure 2 times. Notes: Sputum is highly viscous. Strictly follow the instructions as described. Adding too much or too little sample material can produce unreliable test results.
Peel the aluminum seal from the extraction tube.
Place 0.6ml of sputum sample in the extraction tube. Notes: Sputum is highly viscous. Strictly follow the instructions as described. Adding too much or too little sample material can produce unreliable test results.
Use the pipette to mix the sputum sample with the extraction fluid 5x.
Press the drip cap firmly into the extraction tube. Wait at least 1 minute for viral antigens to dissolve.

TEST PROCEDURES

Return the test equipment and samples to room temperature (15-30 ° C or 59-86 ° F) before testing.

Tap the bottom of the tube to mix the sample solution
Take a test cassette from the foil pouch and place it on a table. Hold the tube vertically and place 3 drops of the sample solution in the sample well (S) of the test cassette.
Read the result after 15 to 30 minutes. After 30 minutes, the result is considered inaccurate and invalid. Note: DO NOT reinsert the sample solution into the sample well of a used test cassette.

RESULT INTERPRETATION

Positive (+): Red lines appear on both the T and C lines within 15 to 30 minutes.

Negative (-): A red line appears on the C while no red line appears on the T-line in 15 to 30 minutes after sample placement.

Invalid: As long as no red line appears on the C, this indicates that the test result is invalid. The sample must be retested with a different test cassette.

PRODUCT PERFORMANCE

Limit of Detection (LoD): The LoD of this prod