

ALL TEST SARS-CoV-2 og Influenza A+B Antigen Combo Rapid Test (Nasal Swab) Package Insert For self-testing

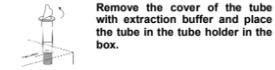
A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen.

For self-testing *in vitro* diagnostic use.

[PROCEDURE]

Wash your hands with soap and water for at least 20 seconds before and after test. Soap and water are not available, use hand sanitizer with at least 60% alcohol.

Remove the cover of the tube with extraction buffer and place the tube in the tube holder in the box.



Nasal swab specimen Collection

- Remove the sterile swab from the pouch. Do not touch the soft tip of the swab.
- Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it against the sides of your nostril for 5-10 times against the nasal wall.

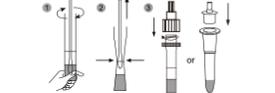
Note: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended. If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab so far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

- Gently remove the swab.
- Using the same swab, repeat step 2 in your other nostril.
- Withdraw the swab.

Specimen Preparation

- Place the swab into the extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against the tube and rotate the swab for 10-15 seconds.
- Remove the swab while squeezing the swab head against the inside of the extraction tube.
- Place the swab in a plastic bag.
- Close the cap or fit the tube tip onto the tube.



ALL TEST Kombineret självtestet SARS-CoV-2 og Influenza A + B antigen (näsprov) Bruksanvisning För självtestet

Kombineret självtestet för kvalitativ detektion av antiprotein i coronavirus SARS-CoV-2 och virus influenza A och influenza B i provtagningsspinnen.

Endast avsett för självtestning *in vitro*.

[UTVÄRDNING]

Våtta händerna med tvål och vatten i minst 20 sekunder före och efter provtagningen. Om tvål och vatten inte finns tillgängligt, använd handsprit med en alkoholhalt på minst 60 %.

Ta av locket på röret med extraktionsbuffert och sätt röret i rörhållaren på kartongen.

Egenprovtagning i näsan

- Ta ut den sterila provtagningsspinnen ur påsen. Vidrör inte pinnens mjuka änd.
- För in provtagningsspinnen i näsborren tills du känner ett lätt motstånd (ca 2 cm upp i näsan). Vrid långsamt på provtagningsspinnen och grunda den mot näsväggen i näsborren 5-10 gånger.

Det här kan kännas obehagligt. För in te provtagningsspinnen djupare i näsan tills du känner ett lätt motstånd eller smärta. Provtagning i näsan om inte rekommenderas inte om nästämman har skadad eller blöder.

Använd ansiktsmask eller munskydd om du ska omgäva andra personer. Tvätta händerna med tvål och vatten efter provtagningen. Om tvål och vatten inte finns tillgängligt, använd handsprit med en alkoholhalt på minst 60 %.

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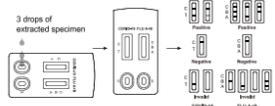
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Testing

- Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- Place the test cassette on a flat and level surface. Insert the specimen extraction tube and add 3 drops of extracted specimen to each sample well(S) of the test cassette and start the timer. Do not move the test cassette while test developing.
- Read the result at 10 minutes. Do not read the result after 20 minutes.



Note: After test is completed, place all the components into plastic bag and tightly sealed, then dispose according to local regulation.

[READING THE RESULTS]

Please carefully follow your local COVID guidelines/requirements.

POSITIVE SARS-CoV-2* Two colored lines appear in the COVID-19 window. One colored line should be in the control region (C) and another colored line should be in the test region (T).

POSITIVE Influenza A: Two colored lines appear in the FLU A+B window. One colored line should be in the control region (C) and another colored line should be in the test region (T).

POSITIVE Influenza B: Two colored lines appear in the FLU A+B window. One colored line should be in the control region (C) and another colored line should be in the test region (T).

INVALID: Control line does not appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test.

[PRECAUTIONS]

Please read all the information in this package insert before performing the test.

For self-testing *in vitro* diagnostic use only. Do not use after expiration date.

Do not eat, drink or smoke in the area where the specimens or kits are handled.

Do not drink the buffer in the kit. Carefully handle the contents of SARS-CoV-2 and influenza A and influenza B. The SARS-CoV-2 and influenza A and influenza B nucleoproteins antigens in human swab specimens are highly infectious.

[PRINCIPLES]

The SARS-CoV-2 and influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein, influenza A and influenza B nucleoproteins antigens in human swab specimens.

[CAUTIONS]

- Performance was evaluated with nasal swab specimens only, using the procedures provided in this package insert.
- The SARS-CoV-2 and influenza A+B Antigen Combo Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 and/or influenza A/Influenza B antigens in the specimen.
- If the test result is negative or non-reactive and clinical symptoms persist, it is recommended to test again with a new kit. Negative results do not rule out SARS-CoV-2 infection. In particular, in those subjects with a positive result, an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
- Failure to follow these procedures may affect test results.
- False negative results may occur if a specimen is improperly collected or handled. False negative results may occur if inadequate levels of virus are detected in the specimen.

[PERFORMANCE CHARACTERISTICS]

Clinical performance

The SARS-CoV-2 results means it is very likely you have COVID-19 and/or influenza A/Influenza B. Immediately go into self-isolation in accordance with the local guidelines.

NEGATIVE: One colored line appears in the control region (C). No other colored line appears in the test line region (T/B/A).

You are unlikely to have COVID-19 and/or Influenza A/Influenza B. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19 and/or Influenza A/Influenza B. However, it is possible for this test to give a positive result that is incorrect (a false positive) in some people with COVID-19 and/or Influenza A/Influenza B even though the test is negative. In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days. If positive results are indicated in the control region, it has been precisely detected in all phases of an infection.

Even with a negative test result, distance and hygiene rules must be observed, migration/traveling, attending events and etc. should follow your local COVID/influenza guidelines/requirements.

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The SARS-CoV-2 and influenza A+B Antigen Combo Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein, influenza A and influenza B nucleoproteins antigens in human swab specimens.

SARS-CoV-2, Influenza A and Influenza B virus that causes COVID-19 and/or influenza with self-collected nasal swab specimens. The test is intended for use in asymptomatic individuals who are suspected of having been infected with COVID-19 and/or influenza A/B. Results are for the detection of SARS-CoV-2 Nucleocapsid protein, Influenza A and Influenza B nucleoproteins antigens. An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results are indicative of the presence of SARS-CoV-2 and/or influenza A/B. Individuals who test positive should self-isolate. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 and/or influenza A/B infection.

[SUMMARY]

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus 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 3-7 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.

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