

SARS-CoV-2 Antigen Rapid Test (Nasal Swab)

REF ACO-1001

No. 14668503 Date 2023-02-23

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in nasal swab specimen. For testing in vitro diagnostic use.

PROCEDURE

Wash your hands carefully before testing according to local regulation about hygiene standard procedures.



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

Nasal Swab Specimen Collection

1. Remove the sterile swab from the pouch.

Note: Do not touch the "cotton" end of the swab.

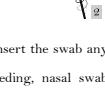


2. Insert the swab into your nostril until you feel slight resistance (approx. 2cm up your nose). Slowly twist the swab, rubbing it along the inside of your nostril for 5-10 seconds.

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

Where 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 need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.



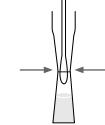
3. Gently remove the swab.

4. Using the same swab, repeat step 2 in your other nostril.

5. Withdraw the swab.

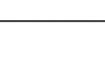
Specimen Preparation

1. Place the swab into the Extraction tube, ensure it is correctly assembled, stir the swab to mix well. Pass the swab head against the tube and rotate the swab for 10-15 seconds.



2. Remove the swab while squeezing the swab head against the inside of the Extraction tube. Place the swab in a plastic bag, tie it.

3. Close the cap or fit the tube top onto the tube.



INTENDED USE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a single-use test kit intended to detect the SARS-CoV-2 antigens with self-collected nasal swab specimens from symptomatic individuals who are suspected of being infected with COVID-19.

An antigen test for the qualitative detection of SARS-CoV-2 antigens in nasal swab specimens. Test results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine if positive results are indicative of the presence of SARS-CoV-2. Individuals who test positive should self-isolate and seek medical advice from their healthcare provider.

Positive results indicate the presence of SARS-CoV-2 infection or co-infection with other viruses respiratory.

Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-19-like symptoms should seek follow up care from their healthcare provider.

SUMMARY

The novel coronavirus belongs to the **B** 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 infected. The incubation period of COVID-19 is 3-7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are also common.

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleoprotein protein antigen in human nasal swab specimens.

PRECAUTIONS

Please read all the information in this user instructions before performing the test.

* For self-testing, do not use after expiration date.

* Do not eat, drink or smoke in the kit. Handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.

* Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil seal has been broken, please do not use.

* This test is intended to be used as a point-of-care test and only repeatedly abnormal results should be discussed with doctor or medical professional.

* Follow the indicated time strictly.

* Do not touch only once. Do not dismantle and touch the test window of the test cassette.

* Test for contact lens wear.

* Wash your hands before and after handling according to local regulation about hygiene standard procedures.

* Please ensure that an appropriate amount of samples are used for testing. Too much sample may lead to false results.

STORAGE AND STABILITY

Storage as packaged in the sealed pouch at room temperature or refrigerated (2-30 °C).

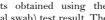
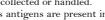
The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not beyond the use-by date.

MATERIALS

Materials Provided

* Test cassette (including (Optional)) * Extraction buffer

* Sterile swab



* Extraction buffer

* Sterile swab

Clinical performance

A clinical trial was conducted with PCR test results obtained using the SARS-CoV-2 Antigen Rapid Test (Nasal Swab) test. The results demonstrated 99.0% specificity and 95.80% sensitivity with an overall accuracy of 97.0%.

INDEX OF SYMBOLS

PCP (nucleoprotein specific) sample number

Positive sample

Negative sample

Total

Corrected

Rate

95.80% Sensitivity: In total 500 PCR confirmed positive samples 479 PCR confirmed samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There 99.0% Specificity: In total 311 PCR confirmed negative samples 308 Test. These samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. The observed accuracy may vary depending on the prevalence of the virus in the test population.

Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered

Testing

1. 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 the extraction.

Place the test cassette on a flat and level surface.

2. Invert the specimen extraction tube and add 3 drops of extracted specimen to the sample well (S) of the test cassette and start the timer. Do not move the test cassette during the test development.

3. Read the result at 15 minutes. Do not read the result after 20 minutes.

4. Remove the cover of the tube with Extraction buffer and place the tube in the tube holder.

5. Wash your hands thoroughly after test disposal.

6. Retire the cap of the tube with tampon de extraction and coloque el tubo en el soporte para tubos.

7. Note: After test is completed, place all the components into a plastic bag (eg biohazard bag) and tightly seal it. Then dispose according to local regulation.

If you are swabbing others, please wear a face mask. With children, you may need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.

8. Lávate bien las manos después de la eliminación de la prueba.

9. Note: No toque el extremo de "a galón" del hisopo.

10. Note: Apriete bien el envase de hisopo.

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SARS-CoV-2 Antigen Rapid Test (Nasal Swab)
SARS-CoV-2-antigensestel (Neusswab)
REF ACO-1001

Gebruikersinstructies
Voor zelftests
Nederland



Een snelle test voor de kwalitatieve detectie van nucleocapside-erecti-antigenen van SARS-CoV-2 die aanwezig zijn in monsters van neusswabs.
Alleen voor zelftests *in-vitro* diagnostisch gebruik.

PROCEDURE

Was uw handen zorgvuldig voor u gaat testen volgens de lokale regelgeving met betrekking tot hygiestandaardprocedures.

Verwijder de dop van het buisje met extractiehopper en plaatst het buisje in de buishouder.

Monsteraframe met neusswabs

1. Haal de steriele neusswab uit de verpakking.
Let op: raak het "katoenen" uiteinde van de neusswab niet aan.

2. Steek de neusswab in uw neusgat tot u lichte weerstand voelt (ongeveer 2 cm in uw neus). Draai de neusswab langzaam en wijfje het 5-10 keer langs de binnenzijde van uw neusgat tegen de neusswab.

Let op: dit kan ongemakkelijk voelen. Breng de neusswab niet dieper in als u sterke weerstand voelt (ongeveer 2 cm in uw neus). Wanneer het neusslijmblaas is beschadigd of bloedt, wordt het niet aanbevolen een monster af te nemen met een neusswab.

Als u bij andere een monster afdient, draag dan een gezichtsmasker. Bij kinderen voor u de neusswab mogelijk niet zo ver in het neusgat te steken. Voor zeer jonge kinderen kan het nodig zijn dat iemand anders het hoofd van het kind stabiel houdt tijdens de monsteraframe.

3. Verwijder de neusswab voorzichtig.

4. Herhaal stap 2 in uw ander neusgat met dezelfde neusswab.

5. Haal de neusswab eruit.

Monsteraframe bereiden

1. Plaats de neusswabs in het extractiehuisje, zorg ervoor dat die de bodem raakt en roer de neusswab om goed te mengen. Druk de kop van de neusswab tegen het buisje in draai de neusswab gedurende 10-15 seconden.

2. Verwijder de neusswab terwijl u de kop van de neusswab tegen de binnenzijde van het extractiehuisje drukt. Plaats de neusswab in een plastic zak.

3. Sluit de dop of plaatst het uiteinde van het buisje terug op het buisje.

BEHOEDIG GEBRUIK

De SARS-CoV-2-antigensestel (neusswab) is een testkit voor sensuele gebruik die is bedoeld voor het detecteren van de SARS-CoV-2-antigenen met behulp van zelligenomen. De resultaten van deze test kunnen alleen worden verkregen door de medische personen die verantwoordelijk zijn voor de gezondheid.

Deze testkit is alleen voor de detectie van SARS-CoV-2-antigenen in de mond en neus.

Beschrijving: Testkit voor de detectie van de SARS-CoV-2-antigenen in de mond en neus.

Testcomponenten:

• Allemaal voor zelftests.

• Een dop voor neusswab.

• Een dop voor mondswab.

• Een dop voor mondswab.