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NADAL®

(Ref. 243103N-05H)

EN

COVID-19 Ag Test

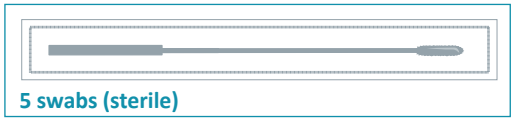
Instructions for use

Antigen rapid test for self-use, for the detection of the COVID-19 pathogen SARS-CoV-2 in nasal swabs.

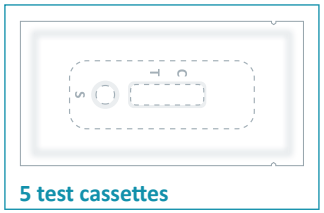
Rapid Tests
Laboratory Diagnostics
Laboratory Service
Consulting & Service

Please carefully read through the package insert.
Carry out the test at room temperature (15-30 °C). For this purpose, the test must first be left at room temperature for 30 minutes.
Do not use the test beyond its expiry date or if any of the packaging is damaged. Children and those under the age of 18 should be assisted by their parents or an authorised adult.

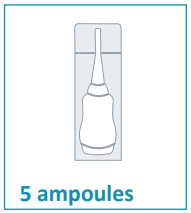
Kit contents



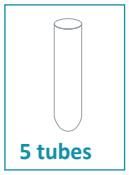
5 swabs (sterile)



5 test cassettes

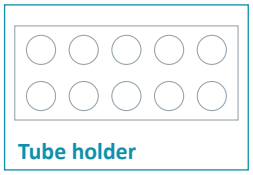


5 ampoules



5 tubes

5 dropper caps



Tube holder

Additional materials required

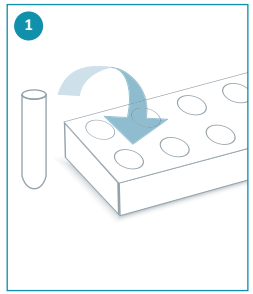
Clock

Video instructions also available.
Simply scan this code.

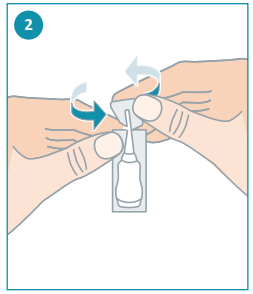
Test procedure

Carry out all steps without interruption!

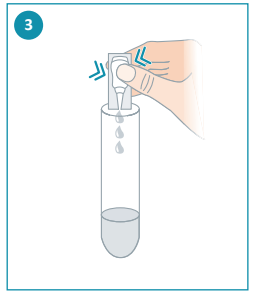
1. Place the tube holder on the table. Place the tube in an opening.



2. Open the ampoule by twisting off the tip.

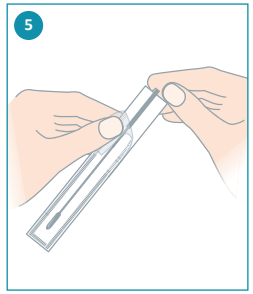


3. Dispense all the liquid into the tube. Squeeze the ampoule whilst holding it over the tube to make sure it's empty.

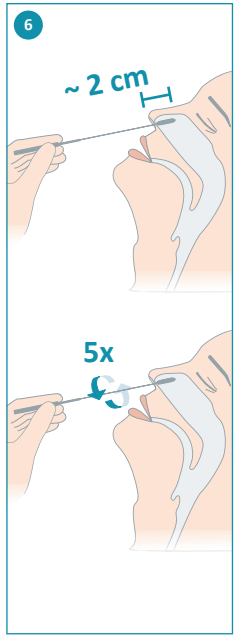


4. Blow your nose briefly into a tissue.

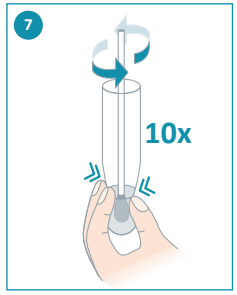
5. Open the swab packaging. To do this, pull apart the loose ends of the packaging. Remove the swab by its shaft. Do not touch the tip of the swab.



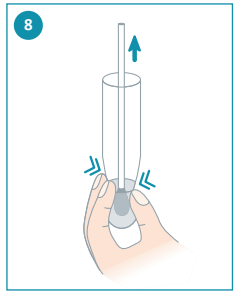
6. **Sample collection**
   a) Insert the swab approx. 2 cm into the nostril.
   b) Gently rotate the swab 5 times against the nasal wall. The swab should be in your nostril for 15 seconds.
   c) Remove the swab from your nose whilst lightly rotating it.
   d) Using the same swab, repeat the process in your other nostril, also for 15 seconds.



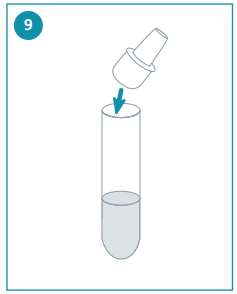
7. Put the swab into the tube. Rotate the swab whilst squeezing the lower part of the tube 10 times, so that a slight pressure is applied to the swab tip.



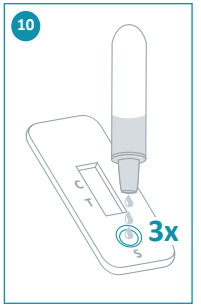
8. Remove the swab, pressing the sides of the tube together to extract as much liquid as possible from the swab.



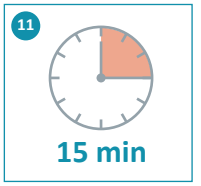
9. Attach the dropper cap to the tube. Make sure that it is on properly.



10. Open the foil packaging and remove the test cassette. Place the test cassette on a flat, level surface. **Squeeze lightly** to dispense 3 drops of fluid into the round sample well (S) of the test cassette (NOT the elongated result field).



11. Look at the clock. Read the results after **15 minutes**! The results are no longer valid after more than 20 minutes.



Result interpretation

Be sure to read the test results in a well-lit environment.

Negative test result:
Only the **C-line** appears in the result field. No virus has been detected, there is no indication of infection with SARS-CoV-2.

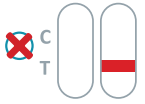
Please note: A negative result does not rule out the possibility of infection. Continue to adhere to current regulations and safety measures when coming into contact with others. In the event of a suspected infection, repeat the test after 1-2 days, as not all phases of the infection are easily detectable.

Positive test result:
Both the **C-line** and the **T-line** appear in the result field. This indicates an infection with SARS-CoV-2.

Please note: The intensity of the T- or C-line may differ. Even a very weak or irregular line indicates a positive test result!

Note: Immediately contact your GP or healthcare centre by phone, as results will need to be confirmed using a PCR test. Adhere to your local guidelines regarding self isolation.

Invalid:
No **C-line** appears. The result is invalid and indicates an error in the test procedure.



Note: Please carry out a new test. In the event of further invalid results, contact your GP or a COVID-19 test centre.

Intended use

The NADAL® COVID-19 Ag Test detects components (viral nucleocapsid protein) of COVID-19 SARS-CoV-2 pathogens. Samples comprise of nasal secretions taken from the lower nasal passage (anterior nasal swab), which are collected with the help of the swabs provided. This test is suitable for self-use. The test results offer a first indication of whether an infection is present, and how high the risk of transmission is for other people. Negative results do not rule out infection with absolute certainty, as low viral concentrations - such as those seen in the early stages of infection - may not be sufficient to be picked up by the test.

In order to ensure a reliable test result, read the instructions regarding sampling and test procedure thoroughly beforehand. Pay close attention to the 'Test limitations' section, as well as the 'Frequently asked questions' section, to find out what to do in the case of a positive/negative test result. **This antigen test is not for use by individuals looking to bypass or shorten their quarantine period.**

Background

COVID-19 (also known as Coronavirus disease) is an infection caused by the recently discovered coronavirus SARS-CoV-2. The most common symptoms of COVID-19 are fever, a dry cough, fatigue, shortness of breath, a sore throat and headaches. Some patients may have myalgia, chills, nausea, nasal congestion and diarrhoea. The virus is highly contagious and is transmitted via respiratory droplets, which are exhaled by people breathing, coughing, sneezing or talking. An infection can occur before the onset of symptoms. Even an asymptomatic person can be infectious. In symptomatic patients, the viral concentration is at its highest at the onset of symptoms. High viral concentrations will be reliably detected by a rapid test, meaning that highly infectious people can be identified. Low concentrations can lead to a negative test result, even in the presence of the infection. Negative results can therefore not exclude the possibility of infection.

Storage

The test should be stored in its original packaging at room temperature (2-30°C). The kit components (swab, ampoule, test cassette) should be first be opened at the beginning of the test procedure.

Notes for safe usage:

- Keep test kit out of reach of children
- This product is an *in-vitro* diagnostic test. The kit and its components must not be swallowed.
- In order to avoid mistakes in sample collection, test procedure or result interpretation, carefully read through the package insert beforehand. In order to avoid distractions and contamination, ensure a clean and calm environment before beginning the test. Strictly adhere to temperature and time specifications.
- Use only the swab provided for sample collection. Other swabs or cotton buds are not suitable and can lead to incorrect results.
- Only use kit components if the original packaging is undamaged.
- Large amounts of blood in nasal secretions can falsify results and difficulties in discerning weak lines.
- Do not use the test beyond its expiry date.
- This product is for single use only and cannot be reused.
- Used tests and kit components can be disposed of in ordinary household waste.
- Please be sure to wash your hands after carrying out the test.
- The test contains materials of animal origin (e.g. antibodies). If the test is carried out in accordance with the instructions given in the package insert, the used test components pose no risk of infection.

Test limitations

- The possibility of incorrect test results cannot be ruled out. Errors in carrying out the test procedure, faulty tests or sample collection during a period of low viral load can be contributing factors. Please follow the instructions given in the package insert and adhere closely to all specifications and reading times. Pay close attention to what to do in the event of a positive and negative result.
- Negative test results reflect only a moment in time, as they can also occur at the beginning of an infection when the viral load is still low. Tests should therefore be repeated at regular intervals - ideally on a daily basis.
- The test only enables a differentiation between positive and negative results. It is not suitable for the determination of viral load. Even a weak test line signifies infection, and indicates that the individual is highly contagious.

Test principle

This rapid test detects virus proteins with the help of antibodies. One of the antibodies is marked with colour and migrates along the test along with the sample.

If the virus concentration is high enough, the antibody remains in the T-line region, causing a coloured line to appear. This means the test result is positive.

If the sample contains no virus, or if the concentration is too low, no T-line will appear. This means the test result is negative.

Whatever the result, the test must produce a C-line. This line forms regardless of the virus concentration, and indicates that the test is functioning properly. If no C-line forms, the test result is invalid.

Technical data

Product name

NADAL® COVID-19 Ag Test

Detection reaction components

Anti-SARS-CoV-2 antibodies, which specifically detect the nucleocapsid protein

Sample material

A freshly obtained nasal swab, taken using the swab provided

Performance characteristics

The NADAL® COVID-19 Ag Test was evaluated using clinical nasal swab specimens whose status was confirmed by RT-PCR. The results are presented in the following table:

		RT-PCR, C_t<30		
		Positive	Negative	Total
NADAL® COVID-19 Ag Test	Positive	96	0	96
	Negative	6	138	144
	Total	102	138	240

Diagnostic sensitivity: 94.1 % (C_t<30)*
(95 % CI: 87.64% - 97.81%)
(Measurement for the probability that the test correctly identifies a person with COVID-19 as positive.)

Diagnostic specificity: >99.9 %*
(95 % CI: 97.36% - 100%)
(Measurement for the probability that the test correctly identifies a person as negative.)
*Results of a clinical study carried out by trained personnel.

Frequently asked questions

How does the NADAL® COVID-19 Ag Test detect the coronavirus?

The coronavirus is made up of various proteins, one of which is the nucleocapsid protein. It surrounds the RNA, i.e. the genetic information of the virus. The NADAL® COVID-19 Ag Test contains antibodies which can recognise the coronavirus' nucleocapsid protein. This recognition follows the 'lock-key' principle, as antibodies and nucleocapsid proteins fit together exactly.

How does the NADAL® COVID-19 Ag Test work?

If the coronavirus (SARS-CoV-2) is present in the obtained sample, its nucleocapsid proteins react with the coloured antibodies in the test and cause the T-line to form. Regardless of nucleocapsid proteins, a C-line must always appear. This indicates that the test has worked properly. If no C-line appears, the test has not functioned properly and the result is invalid. The presence of a C-line as well as a T-line indicates a possible SARS-CoV-2 infection. If only the C-line appears, no virus has been detected. In principle, the test functions in the same way as a pregnancy test.

When can the test be used?

A NADAL® COVID-19 Ag Test can be carried out both in the case of symptoms or if transmission is suspected. Rapid testing is also recommended prior to contact with multiple individuals or those belonging to risk groups. In such cases, the test can be useful in identifying those with a higher viral load who are highly contagious - even if they themselves do not feel ill. Both the concentration of the coronavirus and the nucleocapsid proteins can vary throughout the course of illness. It can therefore be the case that the rapid test cannot detect the nucleocapsid protein, even though an individual is still contagious. A negative test result does not rule out the possibility of infection.

What happens when I transfer fewer/more than 3 drops into the sample well?

In order that the test functions correctly, exactly 3 drops of sample should be dispensed into the round sample well. If you have accidentally added more/fewer drops into the sample well, the test can no longer function reliably and a new test should be carried out.

If I read the results after more than 20 minutes, is the result still reliable?

No. The test should be read 15 minutes after adding the sample. The result is valid up to 20 minutes after adding the sample. You must strictly adhere to these reading times. If the test is read too late or too early, it can lead to incorrect results. Lines that appear after more than 20 minutes cannot be interpreted as a positive result.

How can I interpret the test if the intensity of the lines is different?

The intensity of the lines plays no role in the evaluation of results. Even a weak T-line should be interpreted as positive.

What does the line marked as 'C' mean?

'C' does NOT stand for COVID-19 or corona! The C-line is the control line, and signifies that the test has been carried out correctly. It indicates that a sufficient amount of sample has been added and that the liquid has been properly absorbed by the test. If the line doesn't appear, the test has not functioned properly. This means that the test result should not be interpreted (it is invalid).

Can the results be incorrect?

In a clinical study, the test identified 96 out of 102 infected individuals with a positive result (diagnostic sensitivity). Of those test subjects who weren't infected, 138 out of 138 were identified with a negative result (diagnostic specificity). These results were used to calculate diagnostic sensitivity (94.1%) and diagnostic specificity (>99.9%). Nevertheless, the test is dependent on a sufficient virus concentration. In the case of a new or subsiding infection, the test can produce a negative result even when the individual is still contagious. For this reason, even in the event of a negative result, compulsory hygiene methods should be observed at all times.

Can medications influence test results?

The effects of different medications and substances on our NADAL® COVID-19 Ag Test have already been tested and were found to have no influence on the test results. However, effects from medication cannot be ruled out. For further information, please see the section labelled 'Studies on interfering factors'.

Does the test only detect COVID-19?

The NADAL® COVID-19 Ag Test was tested with various pathogens, such as influenza viruses ('flu'), various bacteria and seasonal coronaviruses ('cold viruses') None of these pathogens were detected using the NADAL® COVID-19 Ag Test. For further information, please see the section labelled 'Cross reactivity studies'.

Clinical studies

In a clinical study, nasal swabs were taken from 240 symptomatic test subjects and examined in parallel using rapid tests and RT-PCR. 138 negative samples were correctly identified as negative. Of 102 samples found to be positive by RT-PCR (Ct<30), the test recognised 96 as positive. These results were used to calculate diagnostic sensitivity (94.1%) and diagnostic specificity (>99.9%), more about which is written in 'Technical Data'.

Test detection limit

The test detects even low levels of concentration of the nucleocapsid protein (0.4 ng/mL). The virus is detected from a concentration of $2 \times 10^{2,4}$ $TCID_{50}$/mL (TCID = Tissue Culture Infection Dose).

Studies on interfering factors

The effects of different medications and substances on our NADAL® COVID-19 Ag Test have already been tested. This included 3 over-the-counter nasal sprays, 3 over-the-counter mouthwashes, 3 over-the-counter throat drops, the active ingredients of widely used painkillers such as aspirin (acetylsalicylic acid) and paracetamol (4-acetamidophenol), flu remedies (Tamiflu® (Oseltamivir), Relenza® (zanamivir), rimantadine), nasal decongestants (oxymetazoline, phenylephrine), asthma drug albuterol, cough syrup (guaiacol glyceryl ether), an antibiotic (mupirocin), mucus (mucin), and other drugs or their active ingredients (chlorpheniramine, dexamethasone, dextromethorphan, diphenhydramine, doxylamine succinate, flunisolide, phenylpropanolamine, tobramycin, triamcinolone). No influence on test results was observed.

Cross reactivity studies

A study was undertaken to determine whether the presence of other pathogens would cause the test to produce a false-positive result (cross reactivity) The following pathogens were examined: 4 common seasonal coronaviruses (not SARS), influenza A and influenza B (various virus types), human respiratory syncytial virus, adenovirus, rhinovirus, Epstein-Barr virus, parainfluenza virus types 1,2,3, norovirus, mumps virus, measles virus, human metapneumovirus, Coxsackie virus type A16, *Candida albicans, Haemophilus influenzae, Mycobacterium tuberculosis, Chlamydia pneumoniae, Legionella pneumophila, Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus Group C, Streptococcus pneumoniae, Staphylococcus aureus, Bordetella parapertussis, Mycoplasma pneumoniae*,MERS-CoV.

All results were negative. This means that a positive result is most likely due to SARS-CoV-2 and not caused by another pathogen.

Precision study

When identical samples of differing concentrations (controls) are tested, >99 % of professional user tests indicate the expected result. Studies on repeatability and reproducibility indicate that the test functions reliably.

Symbol			
	Pay attention to the package insert		For single use only
IVD	*in-vitro* diagnostics		Use before
+2°C +30°C	Temperature limit	REF	Product code
LOT	Batch number		Manufacturer
	Suitable for <n> uses	CE	CE conformity mark

Additional materials provided in accordance with 93/42/EWG: Sterile swab CE 0197

Jiangsu Changfeng Medical Industry Co., Ltd., Touqiao Town, Guangling District Yangzhou, 225109 Jiangsu, China
(EU-representative: Llins Service & Consulting GmbH, Obere Seegasse 34/2, 69124 Heidelberg, Germany)

IVD

Test for self-use – Special approval for self-testing in accordance witho §11 MPG in Germany (BfArM GZ: 5640-S-045/21)

Test zur Eigenanwendung – Befristete Sonderzulassung zur Eigenanwendung nach §11 MPG in Deutschland (BfArM GZ: 5640-S-045/21)

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