INSTRUCTION MANUAL

REF **3987**

March 15, 2021

GA CoV-2 Antigen Rapid Nasal

- 20 determinations -

CE

IVD *In-vitro* diagnostic device

Rapid immunochromatographic test for
the detection of SARS-Coronavirus 2 (COVID-19)
Antigen in human nasal specimen

REF	Catalogue number	**LOT**	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction	D	Biological risk
Σ	Number of tests		Do not reuse

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INTENDED USE

GA CoV-2 Antigen Rapid Nasal is used for the qualitative determination of SARS-Coronavirus 2 (COVID-19) Antigen in human nasal specimen. The test is intended for use by trained clinical laboratory personnel.

Severe acute respiratory syndrome (SARS) is caused by novel coronavirus 2 (SARS-CoV-2, formerly "2019-nCoV"). SARS-CoV-2 is a zoonotic single-stranded RNA virus with positive polarity that belongs to the coronavirus family. It is classified in the beta-coronavirus genus, which also includes SARS-CoV (2003) and MERS-CoV (2012). Of the coronavirus structural proteins envelope, membrane, spike and nucleocapsid, the latter two are the most important immunogens.

Infection with SARS-CoV-2 can lead to a respiratory disease called COVID-19 (Coronavirus Disease 2019). It occurred in humans since late 2019 in Hubei Province, China, and spread rapidly with pandemic proportions around the world.

Patients infected with SARS-CoV-2 may remain asymptomatic or develop only mild upper respiratory symptoms similar to those of a cold or flu. Others develop pneumonia and ARDS requiring intensive care intubation, and may suffer complications that can be fatal. It can take up to 14 days after exposure to SARS-CoV-2 for symptoms to appear. Infected individuals can pass on the infection regardless of clinical symptoms. In addition to testing the genetic material of the virus using the polymerase chain reaction (PCR), the virus can also be detected directly immunologically. A rapid test provides a result after 15 minutes.

The results are used to detect SARS-CoV-2 antigens, which are generally detectable in upper respiratory tract samples during the acute phase of infection. Although positive results indicate the presence of viral antigens, clinical correlation with patient history and other diagnostic information is required to determine infection status. The pathogen detected may not be the definitive cause of current illness for the patient, as positive results with COVID-19 Antigen Rapid Test do not rule out bacterial infection or co-infection with other viruses.
Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Therefore, negative results should be treated as suspected and confirmed with a molecular assay if necessary for patient management.

Zhu N. et al. A Novel Coronavirus from Patients with Pneumonia in China, 2019. N Engl J Med. 2020. doi:10.1056/NEJMoa2001017 (2020).
Corman V.M. et al. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveill. https://doi.org/10.2807/1560-7917.ES.2020.25.3.2000045 (2020).
WHO pandemic statement. http://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-apandemic. Visited on April 8th, 2020.
Zhang J. et al. Evolving epidemiology and transmission dynamics of coronavirus disease 2019 outside Hubei province, China: a descriptive and modelling study. The Lancet, Infectious Diseases DOI:https://doi.org/10.1016/S1473-3099(20)30230-9 (2020)

PRINCIPLE OF THE TEST

The GA CoV-2 Antigen Rapid Nasal is a rapid immunochromatographic test for the qualitative determination of SARS-CoV-2 antigen.

The SARS-CoV-2 antibody is coated in the area of the test line T. During the test, the sample reacts with the particles coated with SARS-CoV-2 antibodies. This complex migrates through the membrane by capillary action and reacts with the SARS-CoV-2 antibody in the test line region. If the sample contains SARS-CoV-2 antigens, a coloured line appears in the test line region as a result. If the sample contains no antigens against SARS-CoV-2, no coloured line appears in the test line region, indicating a negative result. A second coloured line in the control line region C is used as a procedural control, which appears when the sample volume is applied correctly and the membrane is sufficiently moistened.

TEST COMPONENTS for 20 determinations

Test cassettes, coated with antibodies to SARS-CoV-2 Nucleocapsid (conjugated to microparticles and immobilized at the membrane)	20 separetely sealed
Specimen Collection Tubes Filled with extraction buffer	20
Sterile swabs	20

Materials required but not provided

- timer

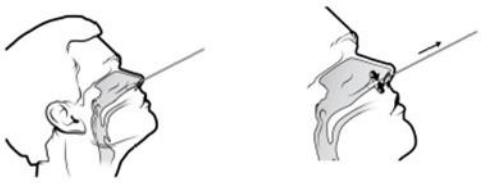
Shelf live and storage

The expiry date of the tests is indicated on the label. Do not use the test after the expiry date.

Until use, store the test at 2-30°C in the sealed packages.

SAMPLE COLLECTION

1. Tilt the patient's head back 70 degrees.
2. Insert the swab about 2 to 2.5 cm deep into the nostril while gently turning it (until resistance is felt on the turbinates).
3. Turn the swab five times against the nasal wall and then slowly remove it from the nostril.
4. Repeat the sampling in the second nostril with the same swab.

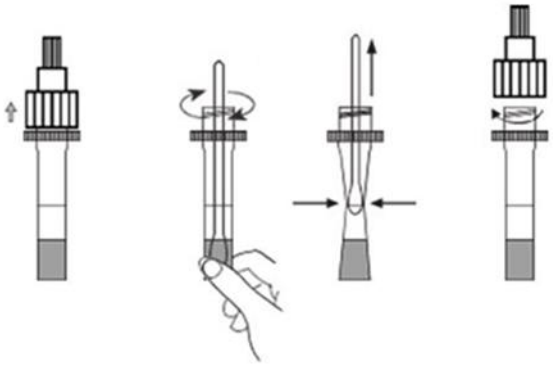


Test swab samples as soon as possible after collection!

If the swabs are not processed immediately, they should be placed in a dry, sterile and tightly closed plastic tube for storage. Based on data generated by the influenza virus, the swab sample was stable up to 8 hours at room temperature and 24 hours at 2-8°C.

SAMPLE PREPARATION

5. Unscrew the cap of the sampling tube.
6. Insert the swab specimen into the specimen collection tube Press against the inner wall of the tube and agitate the swab for approximately 10 times while pressing the swab head against the inner wall of the tube to release the antigens in the collection tube.
7. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab

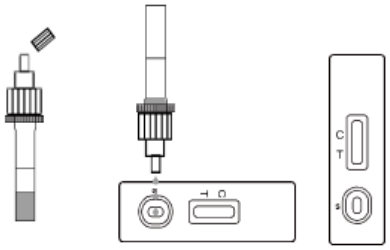


After extraction the samples are stable for 1 h at room temperature or 24 hours at 2-8°C.

ASSAY PROCEDURE

If stored in a cool place, bring the test cassette to room temperature (15-30°C) before performing the test.

1. Remove the test device from the sealed pouch and use it within one hour. For best results, perform the test immediately after opening the pouch.
2. invert the sample collection tube and add 2 drops of the extracted sample into the sample well (S) and then start the timer.
3. wait until the coloured line(s) appear(s) Read the result after 15 minutes. Do not interpret the result after 20 minutes.

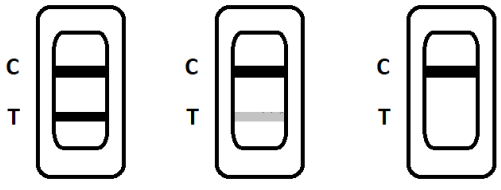


INTERPRETATION OF RESULTS

In the result window, a colour band appears as a control line at position C if the test has run correctly. A colour band appears at position T if the viral antigen is detected.

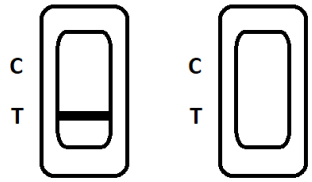
Positive:
2 visible lines appear in the result window. The line in the region T indicates the presence of the CoV-2 antigen in the sample. The colour intensity in the test line region (T) varies depending on the amount of antigen present in the sample. Therefore, any shade of colour in the test line region (T) should be considered positive.

Negative:
Only one coloured line appears in the control region C. There is no coloured line in the test line region T.



Positive Positive Negative

Invalid result
The colour line in region C does not appear. Insufficient sample volume or incorrect test performance are possible causes for the control line not appearing. Check the procedure and repeat the test with a new cassette.



Internal Quality control

A coloured line that appears in the control region (C) is an internal positive procedural control. It confirms sufficient sample volume and correct process engineering. A clear background is an internal negative procedural control. If the test works properly, the background in the result area should be white to light pink and should not affect the readability of the test result.

External Quality control

Control materials are not included in this kit. However, in accordance with Good Laboratory Practice (GLP), positive/negative controls are recommended.

Limitations of Method

1. The test procedure and the interpretation of the test result must be carried out exactly according to the test instructions. Proper specimen collection is critical for optimal test performance. Failure to follow the procedure can lead to inaccurate results.
2. The performance of the GA CoV-2 Antigen Rapid Nasal has been evaluated using only the procedures described in this package insert. Changes to these procedures may alter the performance of the test. The result may be affected by Viral Transport Media (VTM). Extracted specimens for PCR testing cannot be used for testing.
3. The GA CoV-2 Antigen Rapid Nasal is intended for in vitro diagnostic use only. This test should be used to detect SARS-CoV-2 antigens in human nasopharyngeal specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with the clinical presentation and results of other laboratory tests. This qualitative test cannot determine the quantitative value or rate of increase of SARS-CoV-2 antigen concentration.
4. The GA CoV-2 Antigen Rapid Nasal only indicates the presence of SARS-CoV-2 antigens in the specimen and should not be used as the sole criterion for the diagnosis of SARS-CoV-2 infection.
5. Results obtained with the test should be considered in conjunction with other clinical findings from other laboratory tests and evaluations.
6. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended that the patient be re-sampled and re-tested a few days later or checked with a molecular diagnostic test to rule out infection in these individuals.
7. The test will show negative results under the following conditions: The titre of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
8. Negative results do not exclude infection with SARS-CoV-2, especially in persons who have been in contact with the virus. Follow-up testing with molecular diagnostics should be considered to rule out infection in these individuals.
9. Blood or excess mucus on the swab sample may interfere with the test performance and lead to a false positive result.
10. The accuracy of the test depends on the quality of the swab sample. False negative results may result from improper specimen collection or storage.
11. Positive results of COVID-19 may be due to infection with non-SARS CoV-2 coronavirus strains or other interference factors.

ASSAY PERFORMANCE

Detection limit

The limit of detection (LOD) of the GA CoV-2 Antigen Rapid Nasal is 100 pg/mL recombinant SARS-COV-2 nucleocapsid protein.

Comparison with Reference method

The GA CoV-2 Antigen Rapid Nasal was compared with results of the RT-PCR reference method using nasal swab samples from patients. The samples were considered positive if RT-PCR showed a positive result. Samples were considered negative if RT-PCR showed a negative result.

		RT-PCR		Total
		Positive	Negative	
GA CoV-2 Antigen Rapid Nasal	Positive	98	4	102
	Negative	4	496	500
Total		102	500	602

Relative Sensitivity	96.1%; 95% CI: (90.26% - 98.92%)
Relative Specificity	99.2%; 95%CI: (97.96% - 99.78%)
Agreement	98.7%; 95%CI: (97.40% – 99.42%)

Cross reactivity

The following organisms were tested and all were found negative using the GA GA CoV-2 Antigen Rapid Nasal:

Human coronavirus 229E	Human Metapneumovirus
Human coronavirus HKU1	Human RSV
Human coronavirus OC43	Human Enterovirus
Human coronavirus NL63	Human Rhinovirus
MERS-CoV	Adenovirus
Influenza A H1N1 (2009) virus	Avian influenza virus H7N9
Influenza A H3N2 virus	Staphylococcus aureus
Seasonal Influenza A H1N1	Mycoplasma pneumoniae
Influenza B virus (Victoria line)	Neisseria meningitidis
Influenza B virus (Yamagata series)	Streptococcus pneumoniae
Parainfluenza virus	

Interfering substances

The following substances were tested with the GA CoV-2 Antigen Rapid and no interference was observed.

Substance	Concentration
Aspirin	300 µg/l
Ascorbic Acid	200 mg/l
Ibuprofen	2 mg/l
Bilirubin	600 mg/l
Chloramphenicol	30 µg/l

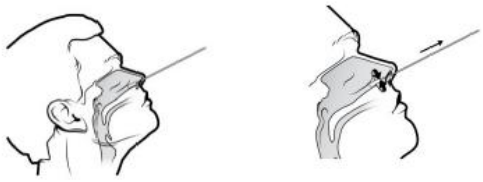
SAFETY PRECAUTIONS

- This reagent kit is for in vitro use only and must be performed by trained laboratory personnel. The working instructions must be strictly followed.
- The test kit should only be used within the specified shelf life.
- Samples and contaminated material must be treated as potentially infectious and disposed of accordingly.
- Since the kit contains potentially hazardous materials, the following precautions should be observed:
  - Do not smoke, eat or drink while handling kit material,
  - Always use protective gloves,
  - Never pipette material by mouth,
  - Wipe up spills promptly, washing the affected surface thoroughly with a decontaminant.

GA CoV-2 Antigen Rapid Test Nasal

Test procedure

1



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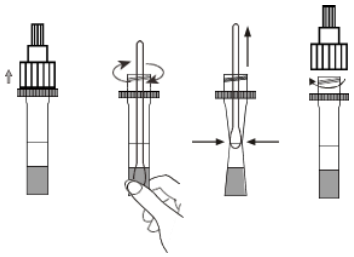

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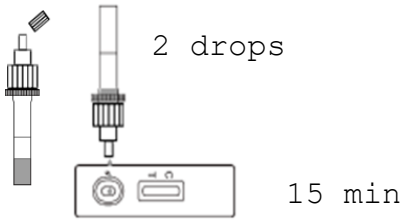

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