INSTRUCTION MANUAL

REF **3980**

November 05, 2020

GA CoV-2 Antigen Rapid

- 20 determinations -

CE

IVD *In-vitro* diagnostic device

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

REF	Catalogue number	**LOT**	Batch code
	Consult accompanying documents		Manufactured by
	Temperature limitation		Use by
	Consult operating instruction		Biological risk

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INTENDED USE

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

Severe acute respiratory syndrome (SARS) is caused by the novel coronavirus 2 (SARS-CoV-2, formerly "2019-nCoV"). SARS-CoV-2 is a zoonotic single-stranded RNA virus with positive polarity, which belongs to the coronavirus family. It belongs to the genus of beta-coronaviruses, 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 in Hubei Province, China, from late 2019 and spread rapidly with pandemic proportions around the world.

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

Results are for the detection of SARS-CoV-2 antigens generally detectable in upper respiratory specimens during the acute phase of infection. Although positive results indicate the presence of viral antigens, clinical correlation with patient history and other diagnostic information are necessary for the determination of the infection status. The detected agent may not be the definite cause for the patient of a current disease, since positive results with GA CoV-2 Antigen Rapid do not rule out bacterial infection or co-infection with other viruses.
Negative results do not preclude 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. Hence negative results should be treated as presumptive 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 Test is a rapid immunochromatographic test for the qualitative determination of SARS-CoV-2 antigen.

A SARS-CoV-2 antibody is coated in the area of the test line T. During the test, virus antigen in the sample reacts with SARS-CoV-2 antibodies coated to coloured particles. 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 cassette coated with antibodies to SARS-CoV-2 (Nucleocapsid), conjugated to microparticles and immobilized at the membran1	20 separately sealed
Extraction buffer in ampoule	20
Specimen collection tube	20
Dropper tip	20
Sterile swabs	20
workstation	1

Materials required but not provided

- timer

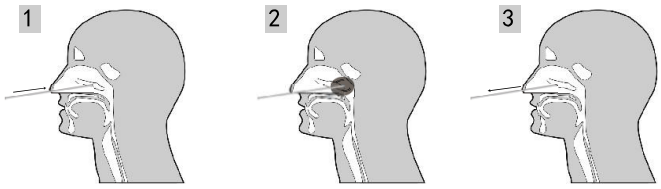
Shelf live and storage

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. insert a sterile swab into the patient's nostril up to the surface of the posterior nasopharynx
2. swab over the surface of the posterior nasopharynx.
3. withdraw the sterile swab from the nasal cavity.

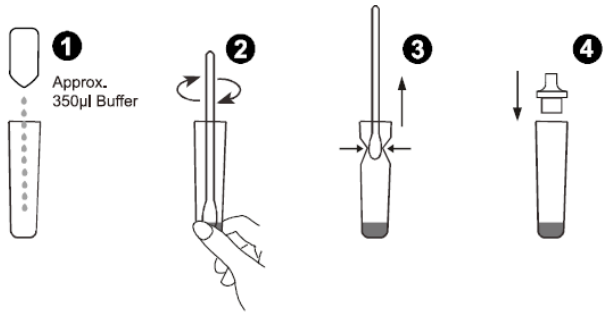


Test swab samples as soon as possible after collection!

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

1. Place the Specimen collection tubes in the workstation. Add the Extraction Buffer (content of one ampoule, 10 drops, approx. 350 µl) to each Sample collection tube, prepare before sample collection.
2. Place the swab specimen in the collection tube. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the tube to release the antigen in the swab.
3. Remove the swab while squeezing the swab head against the inside of the tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.
4. Fit the dropper tip on top of the Sample collection tube.

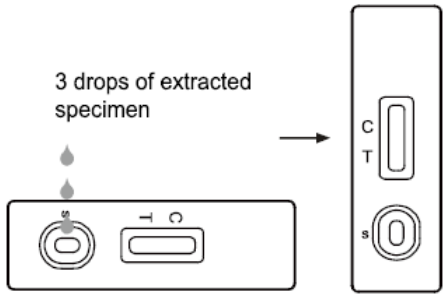


After extraction the samples are stable for 2h at room temperature or 24 hours at 2-8°C.

ASSAY PROCEDURE

If stored in a cool place, bring the test cassette to room temperature 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 3 drops of the extracted sample (approx.75 µl) 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.

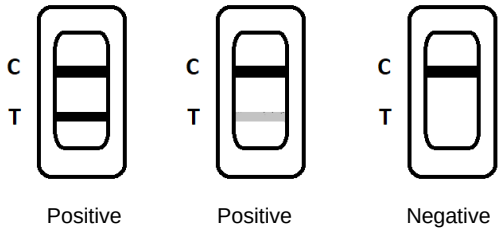


INTERPRETATION OF RESULTS

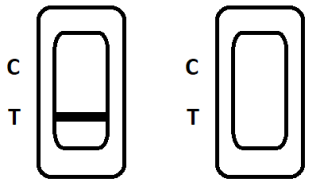
In the result window, a colour band appears as a control line at position C if the test has run correctly. A colour band appears at position T if the viral antigen is detected.

Positive:
2 visible lines appear in the result window. The line in the region T indicates the presence of the SARS-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.



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 sample collection is essential for optimal test performance. Failure to follow the procedure can lead to inaccurate results.
2. The performances of the GA CoV-2 Antigen Rapid were evaluated using the procedures described in this product insert only. Modifications to these procedures may alter the performance of the test. The result may be affect by Viral Transport Media (VTM). Extracted specimens for PCR tests cannot be used for the test.
3. The GA CoV-2 Antigen Rapid is 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 suspected of being infected with SARS-CoV-2 in conjunction with the clinical presentation and results of other laboratory tests. This qualitative test cannot be used to determine either the quantitative value or the rate of increase in the concentration of SARS-CoV-2 antigens.
4. The GA CoV-2 Antigen Rapid 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. The 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 resampled and retested a few days later or checked with a molecular diagnostic test to rule out infection in these individuals.
7. SARS-CoV-2 antigens titres in the sample lower than the minimum detection limit of the test lead to negative results with the GA CoV-2 Antigen Rapid.
8. Negative results do not rule out infection with SARS-CoV-2, especially in persons who have been exposed to the virus. Follow-up tests using 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 procedure and lead to a false positive result.
10. The accuracy of the test depends on the quality of the swab specimen. False negative results may result from improper specimen collection or storage.
11. Positive results of SARS-CoV-2 may be due to infection with non-SARS CoV-2 coronavirus strains or other interference factors.

ASSAY PERFORMANCE

Detection limit

A recombinant SARS-CoV 2 protein was examined in a dilution series to determine the detection limit. The assays were performed according to the package insert.
The detection limit of the GA CoV-2 Antigen Rapid Test was determined as 100 pg/ml of the recombinant protein.

Comparison with Reference method

The GA CoV-2 Antigen Rapid 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	Positive	80	1	81
	Negative	3	120	123
Total		83	121	204
Relative Sensitivity		96.4% (95%CI*: 89.8%~99.2%)		
Relative Specificity		99.2% (95%CI*: 95.5%~99.9%)		
Accuracy		98.0% (95%CI*: 95.1%~99.5%)		

Diagnostic Specificity

The GA CoV-2 Antigen Rapid Test has been tested with the following strains of virus. At the concentrations listed, no detectable line was observed in any of the test line regions:

Description	Test level
Adenovirus type 3	3.16 x 10^4 TCID50/ml
Adenovirus type 7	1.58 x 10^5 TCID50/ml
Human coronavirus OC43	2.45 x 10^6 LD50/ml
Human coronavirus NL63	1 x $10^{5.07}$ U/ml
Influenza A H1N1	3.16 x 10^5 TCID50/ml
Influenza A H3N2	1 x 10^5 TCID50/ml
Influenza B	3.16 x 10^6 TCID50/ml
Human Rhinovirus 2	2.81 x 10^4 TCID50/ml
Human Rhinovirus 14	1.58 x 10^6 TCID50/ml
Human Rhinovirus 16	8.89 x 10^6 TCID50/ml
Measles	1.58 x 10^4 TCID50/ml
Mumps	1.58 x 10^4 TCID50/ml
Parainfluenza virus 2	1.58 x 10^7 TCID50/ml
Parainfluenza virus 3	1.58 x 10^8 TCID50/ml
Respiratory syncytial virus	8.89 x 10^4 TCID50/ml

TCID50 = Tissue Culture Infectious Dose is the dilution of the virus that can be expected to infect 50% of the inoculated culture vessels under the test conditions.
LD50 = Lethal Dose is the virus dilution that can be expected to kill 50% of the inoculated mice under the test conditions.

Cross reactivity

The following organisms were tested at 1.0x10^8 org/ml and all were found negative using the GA CoV-2 Antigen Rapid.

Arcanobacterium	*Pseudomonas aeruginosa*
Candida albicans	*Staphylococcus aureus subspaureus*
Corynebacterium	*Staphylococcus epidermidis*
Escherichia coli	*Streptococcus pneumoniae*
Moraxella catarrhalis	*Streptococcus pygenes*
Neisseria lactamica	*Streptococcus salivarius*
Nesseria subllava	*Streptococcus sp group F*

Precision

Intra- and inter-Assays variability has been determined testing negative, weak and strong positive SARS-COV-2 Antigen specimens with three different lots of GA CoV-2 Antigen Rapid. Ten replicates of each specimen were tested each day for 3 consecutive days. The specimens were correctly identified for >99% of the time.

SAFETY PRECAUTIONS

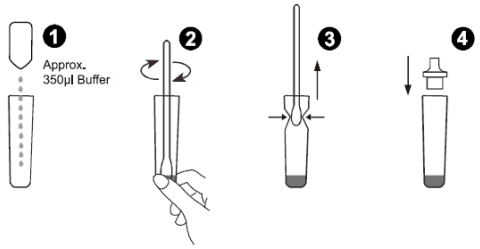
- This reagent kit is for in vitro use only and must be performed by trained laboratory personnel. The working instructions must be strictly followed.
- The test kit should only be used within the specified shelf life.
- Samples and contaminated material must be treated as potentially infectious and 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 PROCEDURE

1

2



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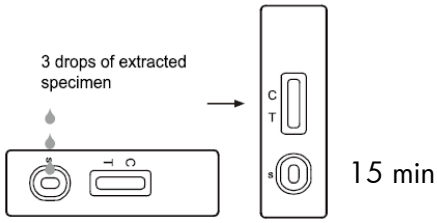

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