

CoviGnost AG test device

TEST DEVICE FOR RAPID DETECTION OF
SARS-CoV-2 ANTIGENS PRESENT IN HUMAN NASOPHARYNX



Product code:
COVAG020 - test device, 1x20 tests
COVAG010 - test device, 1x10 tests
COVAG05 - test device, 1x5 tests
COVAG01 - test device, 1x1 test

INTENDED USE

CoviGnost AG test device is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of the disease.

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. The test is intended for use by trained clinical-laboratory personnel.

SUMMARY

COVID-19 is an acute respiratory infectious human disease caused by novel coronavirus SARS-CoV-2 that belongs to the β genus. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptotically infected people can also be an infectious source. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

PRINCIPLE

CoviGnost AG is a qualitative chromatographic immunoassay for the detection of SARS-CoV-2 antigens in human nasopharyngeal swab specimens. There is a test membrane inside of the test covered with SARS-CoV-2 antibody-coated particles. The specimen reacts with SARS-CoV-2 antibody-coated particles in the test, and then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in the test line region. If the specimen contains SARS-CoV-2 antigens, a colored line will appear in the test line region (T) as a result of this. If the specimen does not contain antigens to SARS-CoV-2, no colored line will appear in the test line region, indicating a negative result. To serve as a procedural control, a colored line will always appear in the control line region (C), indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains anti-SARS-CoV-2 antibody as the capture reagent and anti-SARS-CoV-2 antibody as the detection reagent.

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow directions in the package insert may yield inaccurate test results.
2. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
3. Do not eat, drink or smoke in the area where the specimens or kits are handled.
4. Do not use the test if the pouch is damaged.
5. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout in the collection, handling, storage, and disposal of patient samples and used kit contents.
6. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
7. Wash hands thoroughly after handling.
8. Please ensure that an appropriate amount of samples are used for testing. Too large or too small sample size may lead to deviation of results.
9. The used test should be discarded according to local regulations.
10. Humidity and temperature can adversely affect results.

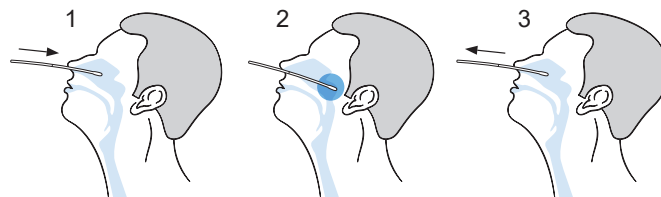
STORAGE AND STABILITY

Store 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 use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

Sampling

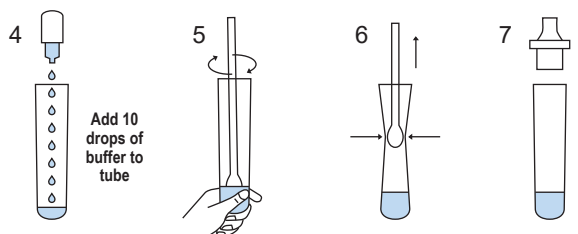
1. Insert a sterile swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
2. Swab over the surface of the posterior nasopharynx.
3. Withdraw the sterile swab from the nasal cavity.



NOTE: Specimens should be tested as soon as possible after collection. If swabs are not been processed immediately, it is highly recommended the swab sample is placed into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in the dry and sterile condition is stable for up to 8 hours at room temperature and 24 hours at 2-8°C.

Specimen preparation

4. Add 350 μ L (10 drops) of extraction buffer to the extraction tube.
5. Place the swab specimen in the extraction 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.
6. Press the swab onto the central part of the tube in order to extract as much fluid from the swab as possible while removing the swab from the tube.
7. Press the tube cap tightly into the test tube.



NOTE: The specimen is stable for 2 hours after extraction at room temperature or 24 hours at 2-8°C.

MATERIALS FOR CONDUCTING THE TEST

Materials provided:

- Test devices
- Sterile swabs
- Instructions for use
- Extraction buffer
- Sampling tubes with cap
- Test tube rack

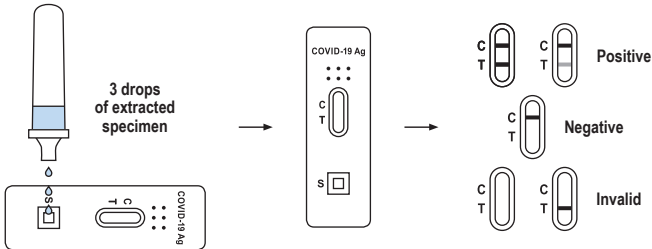
Materials required but not provided:

- Timer

DIRECTIONS FOR USE

Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30°C) prior to 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 opening the foil pouch.
2. Invert the specimen extraction tube and add 3 drops of the extracted specimen (approx. 75µl) to the specimen well (S) and then start the timer.
3. Wait for the colored line(s) to appear. Read the result at 15 minutes. Do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS

(please refer to the illustration above)

POSITIVE: * Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the test region (T). A positive result in the test region indicates detection of SARS-CoV-2 antigens in the sample.

*NOTE: The intensity of the color in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of color in the test region (T) should be considered positive.

NEGATIVE: One colored line appears in the control region (C). No apparent colored line appears in the test line region (T).

INVALID: The control line fails to 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. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

QUALITY CONTROL

Internal quality control

Internal procedural controls are included in the test. A colored line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. A clear background is an internal negative procedural control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

External quality control

Positive/negative controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP), these controls are recommended.

LIMITATIONS

1. The test Procedure and the Interpretation of the test Result must be followed closely when testing for the presence of SARS-CoV-2 antigens in the human nasopharyngeal specimens from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
2. The test is intended for *in vitro* diagnostic use only. This test should be used for the detection of 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 clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
3. The test will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole criteria for the diagnosis of SARS-CoV-2 infections.
4. The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.
5. If the test result is negative or non-reactive and clinical symptoms persist. It is recommended to re-sample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
6. The test will show negative results under the following conditions: The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
7. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing using the PCR method should be considered to rule out infection in these individuals.
8. Excess blood or mucin on the swab specimen may interfere with test performance and may yield a false positive result.
9. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage
10. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains.

EXPECTED VALUES

The test has been compared with a leading commercial RT-PCR test. The correlation between these two systems is no less than 98%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

RT-PCR is used as the reference method for the test. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Nasopharyngeal Swab Specimen

CoviGnost AG test device		RT-PCR		Total
		Positive	Negative	
Test device	Positive	80	1	81
	Negative	3	120	123
Total		83	121	204
Relative sensitivity		96.4% (95%CI*: 89.8%~99.28%)		
Relative specificity		99.2% (95%CI*: 95.5%~99.9%)		
Accuracy		98.0% (95%CI*: 95.1%~99.5%)		

* Confidence intervals

Specificity

CoviGnost AG test device was tested with the following viral strains. No discernible line at either of the test-line regions (T) was observed at these concentrations:

Virus	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
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 ⁵ TCID50/ml
Human rhinovirus 2	2.81 x 10 ⁴ TCID50/ml
Human rhinovirus 14	1.58 x 10 ⁵ TCID50/ml
Human rhinovirus 16	8.89 x 10 ⁵ 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 virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

LD50 = Lethal Dose is the dilution of virus that under the conditions of the assay can be expected to kill 50% of the suckling mice inoculated.

Precision

Intra-Assay and Inter-Assay

Within-run and Between-run precision has been determined by using SARS-CoV-2 standard controls with three different lots of CoviGnost AG test devices. SARS-CoV-2 control samples were tested: negative and samples containing low and high concentration of SARS-CoV-2 antigens. Each control has been tested 10 times for three consecutive days. The specimens were correctly identified >99% of the time.

Cross-reactivity

The following organisms were tested at 1.0x10⁸ org/ml and all found to be negative when tested with the test device:

<i>Arcanobacterium</i>	<i>Neisseria lactamica</i>	<i>Streptococcus pneumoniae</i>
<i>Candida albicans</i>	<i>Neisseria subflava</i>	<i>Streptococcus pyogenes</i>
<i>Corynebacterium</i>	<i>Pseudomonas aeruginosa</i>	<i>Streptococcus salivarius</i>
<i>Escherichia coli</i>	<i>Staphylococcus aureus</i> subsp. <i>aureus</i>	<i>Streptococcus</i> sp. group F
<i>Moraxella catarrhalis</i>	<i>Staphylococcus epidermidis</i>	

BIBLIOGRAPHY

1. Westgard JO, Barry PL, Hunt MR, Groth T. 1981. A multiple-rule Shewhart for quality control in clinical chemistry. *Clinical Chemistry* 1981;27: 493-501

COVAG020, COVAG010, COVAG05, COVAG01, V8, 02.12.2020. PO/MB/MŠ/VF

Do not reuse	Number of tests in package	Keep dry	Storage temperature range
Consult instructions for use	Keep away from sunlight	Use by	European conformity
<i>In vitro</i> diagnostic medical device	LOT Batch code	REF Catalogue number	Manufacturer

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