QuickTestCorona™ COVID-19 Antigen Schnelltest

(Nasopharyngeal Swab)

Package Insert

The QuickTestCorona™ COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens present in the human nasopharynx.

For professional in vitro diagnostic use only.

INTENDED USE

The QuickTestCorona™ COVID-19 Antigen Rapid Test is a rapid chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in nasopharyngeal swab specimens.
An antigen is generally detectable in upper respiratory specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of 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 treated as presumptive and confirmed with a molecular assay, if necessary for patient management. 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.
The QuickTestCorona™ COVID-19 Antigen Rapid Test is intended for use by trained clinical laboratory personnel.

SUMMARY

The novel coronaviruses are part of the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, patients infected by the novel coronavirus are the main source of infection; asymptomatic 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.

TEST PRINCIPLE

The QuickTestCorona™ COVID-19 Antigen Rapid Test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 Antigens in human nasopharyngeal swab specimens. SARS-CoV-2 antibodies are coated in the test line region. During the test, the specimen reacts with SARS-CoV-2 antibody-coated particles. The mixture then migrates upward on the membrane by capillary action and reacts with the SARS-CoV-2 antibody in test line region. If the specimen contains SARS-CoV-2 Antigens, a colored line will appear in test line region 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, indicating that the proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

1. This package insert must be read completely before performing the test. Failure to follow the directions in the package insert may yield inaccurate test results.
2. For professional in vitro diagnostic use only. Do not use after 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 handled.
7. Wash your hands thoroughly after handling specimens.
8. Please ensure that the appropriate amount of the sample is used for testing. Too much or too little sample size may lead to deviation of results.
9. Viral Transport Media (VTM) may affect the test result, do not store specimens in viral transport media; extracted specimens for PCR tests cannot be used for the test.
10. The used test should be discarded according to local regulations.
11. Humidity and temperature can adversely affect the test results.

STORAGE AND STABILITY

Store the test in the sealed original pouch at 2-30°C. The test device can be used until the expiration date printed on the sealed pouch and must remain in the sealed pouch until use.
If the test is stored at 2-8°C, the sealed pouch must be brought to room temperature before use.
The test should be kept away from direct sunlight, heat and moisture.
DO NOT FREEZE! Do not use after the expiration date!

MATERIALS

Materials Provided

• 20 sealed pouches each containing one test cassette and one desiccant • 20 sterile swabs
• 20 specimen collection containers with dropper tips • 1 bottle of extraction buffer • 1 workstation • 1 package insert

Materials Required but not Provided

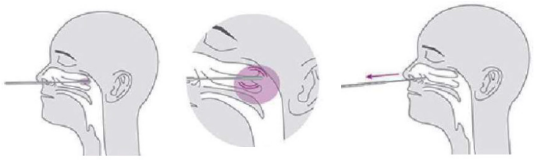
• clock, timer or stop watch

SPECIMEN COLLECTION AND PREPARATION

Specimen Collection

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

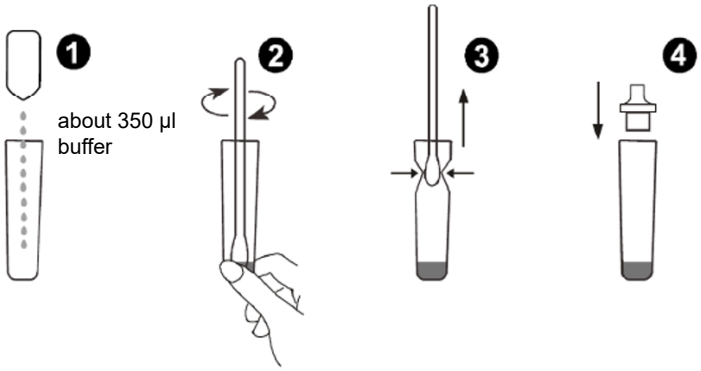


into a dry, sterile, and tightly sealed plastic tube for storage. The swab specimen in dry and sterile condition is stable for up to 8 hours at room temperature and 24 hours at 2 -8 °C. Do not store specimens in viral transport media.

Specimen Preparation

Only the extraction buffer and specimen collection tube provided in the kit is to be used for swab specimen preparation.

1. Place the extraction tube in the workstation. Add approx. 350µl extraction buffer (about 10 drops) to the extraction tube. See fig. 1
2. Insert the swab specimen into the specimen collection tube. Stir the head of the swab for approx. 10 seconds and press it against the inner wall of the tube to release the antigens in the collection tube. See fig. 2
3. Remove the swab while squeezing the sides of the tube to extract liquid from the swab. See fig. 3
4. Place the dropper tip on the sample collection tube. See fig. 4

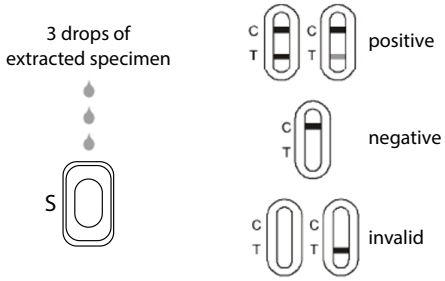


NOTE: The storage of the specimen after extraction is stable or 2 hours at room temperature or 24 hours at 2-8 °C.

TEST PROCEDURE

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 collection 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 TEST RESULTS

(see 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: 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

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.

LIMITATIONS

1. The test procedure and the interpretation of the test results must be followed closely when testing for the presence of SARS-CoV-2 antigens in 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 performance of the QuickTestCorona™ COVID-19 Antigen Rapid Test was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
3. The QuickTestCorona™ COVID-19 Antigen Rapid Test is for in vitro diagnostic use only. This test should be used for 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.
4. The QuickTestCorona™ COVID-19 Antigen Rapid 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.
5. The results obtained with the test should be considered 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 to resample the patient a few days later and test again or test with a molecular diagnostic device to rule out infection in these individuals.
7. The test will show negative results if the titer of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
8. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. Excess blood or mucin on the swab specimen may interfere with the test performance and may yield a false positive result.
10. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample 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.

EXPECTED VALUES

The QuickTestCorona™ COVID-19 Antigen Rapid Test has been compared with a leading commercial RT-PCR test. The correlation between these two systems is no less than 95%.

PERFORMANCE CHARACTERISTICS

Sensitivity, Specificity and Accuracy

The QuickTestCorona™ COVID-19 Antigen Rapid Test has been evaluated with 393 specimens obtained from patients. RT-PCR is used as the reference method for the QuickTestCorona™ COVID-19 Antigen Rapid Test. Specimens were considered positive if RT-PCR indicated a positive result. Specimens were considered negative if RT-PCR indicated a negative result.

Method		RT-PCR		Total
COVID-19 Antigen Rapid Test	Ergebnisse	Positive	Negative	
	Positive	110	2	112
	Negative	5	319	324
Total		115	321	436

Sensitivity: 95.65% (91.9%-99.4%)* **Specificity:** 99.38% (98.5%->99.9%)*
Accuracy: 98.39% (97.2%-99.57%)* *95% Confidence Interval

Sensitivity following Ct-value

For this purpose, QuickTestCorona™ conducted a comparative study with patient samples that were confirmed positive by RT-PCR (including determination of the Ct value) in Austria. In this study the QuickTestCorona™ COVID-19 Antigen Rapid Test achieved the following results:

RT-PCR Ct-Values	Sensitivity of the QuickTestCorona™ COVID-19 Antigen Rapid Test
20-30	100 %
20-31	96.2 %
20-32	96.3 %
20-33	90.0 %
20-34	90.3 %

In the particularly important Ct range between 20 and 30, the QuickTestCorona™ rapid test achieved a perfect result with 100% sensitivity. All samples confirmed as positive by RT-PCR were detected as positive here.

This study clearly shows that the QuickTestCorona™ COVID-19 Antigen Rapid Test is a highly sensitive test for the detection of coronavirus.

Specificity Testing with Various Viral Strains

The QuickTestCorona™ COVID-19 Antigen Rapid Test was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

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
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
RSV	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 = Lethale Dosisis 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 three specimens of a COVID-19 standard control. Three different lots of the QuickTestCorona™ COVID-19 Antigen Rapid Test have been tested using negative SARS-COV-2 Antigen weak specimens and SARS-COV-2 Antigen strong specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified>99% of the time.

Cross-Reactivity

The following organisms were tested at 1.0x10^8 org/ml and all found to be negative when tested with the QuickTestCorona™ COVID-19 Antigen Rapid Test:

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

LITERATURE

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

Consult instructions for use	Tests per kit	Do not use if package is damaged
IVD For In vitro diagnostic use only	Use by	Do not reuse
30°C 2°C Store between 2-30 °C	LOT Lot number	REF Catalogue number

CE

Manufacturer

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Version 1.5aENG, valid from 2020-10-30

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