INSTRUCTION FOR USE

QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test Kit

DIACARTA

For In Vitro Diagnostic (IVD) use.
For use under the Emergency Use Authorization (EUA) only.
Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

PART 1. INTRODUCTION

The QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test Kit is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2. This test is authorized for non-prescription home use with self-collected (unobserved) anterior nasal swab specimens directly from individuals aged 14 years and older, or with adult-collected anterior nasal specimens directly from individuals aged 2 years or older, who are suspected of COVID-19 by their healthcare provider within the first 7 days of symptom onset, or without symptoms or other epidemiological reasons to suspect COVID-19 infection.

PART 2. PACKAGE CONTENT

	1-Test	2-Test	5-Test	20-Test
Test Cassette 	1	2	5	20
Disposable Nasal Swab (Sterile) 	1	2	5	20
Sample Extraction Tube with Solution	1	2	5	20
Extraction Tube Holder	Built-in product packaging	1 	1 	1 
Biohazard Bag 	1	2	5	20
Instruction for Use 	1	1	1	1

MATERIALS REQUIRED BUT NOT PROVIDED

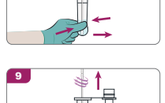
- Timer, Hand sanitizer/Soap, Water, and Tissues.
- Any necessary personal protective equipment including gloves.

NOTE

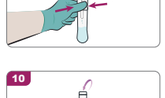
- Allow all Kit components and specimens to reach room temperature between 15°C~30°C prior to testing. If they were previously stored in a cool place (temperature below 8°C).

PART 3. SPECIMEN COLLECTION AND PREPARATION

Wash hands thoroughly (at least 20 seconds) with soap/hand sanitizer and water. This step ensures that the kit will not be contaminated. Dry your hands completely.



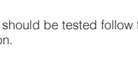
For pack size of 1-test, punch through the perforated circle on the box to form a tube holder. For pack size of 2-test, 5-test and 20-test, the Extraction Tube Holders are provided in the kits.



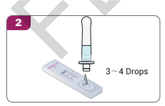
Remove the foil from the top of the extraction solution tube, and place the Extraction Solution Tube in the Extraction Tube Holder.

Tear off the nasal swab's packaging.

Note: A false negative result may occur if the nasal swab specimen is not properly collected.



Carefully insert the entire absorbent tip of the swab into 1 nostril (0.5-0.75 inch). With children, the maximum depth of insertion into the nostril may be less than 0.5 inch, and you may need to have a second person to hold the child's head while swabbing.



Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen to ensure that both mucus and cells are collected. Remove the swab from the nostril. Repeat this in the other nostril using the same swab.

- Do not insert too far into the nostril as this may lead to nasal cavity bleeding or rupture, or other risks.
- A false negative result may occur if the nasal swab specimen is not properly collected.
- The person under 14 years of age should be tested with the assistance of the legal guardian or authorized person.

Immediately place the swab into the Sample Extraction Tube and swirl for 30 seconds.

Vigorously mix the solution by rotating the swab forcefully against the side of the tube at least 5 times when swab submerged in extraction solution.

Squeeze the tube 5 times by hand to ensure that the sample on the sampling swab is fully eluted into the sample extraction solution. (Tips: Squeeze the swab head along the inner wall of the extraction tube above the extraction solution).

Cover the Sample Extraction Tube with the lid, and shake the tube 5 times to mix the liquid thoroughly. Now you have the specimen ready.

Note: For best performance, specimens collected should be tested follow the "Part 4. Test Procedure" immediately after collection.

PART 4. TEST PROCEDURE

Remove the test cassette from the pouch and place on a clean dry surface.

Note: Discard the pouch if the seal is damaged and replace with a new kit

Dispense 3-4 drops (about 70-90μL) of the specimen into the circular sample well (S) on the test cassette.

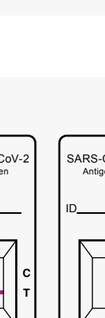
Interpret the test results at 15~20 minutes. Note: False positive or false negative results can occur if test cassette is read before 15 minutes or after 20 minutes.

PART 5. INTERPRETATION OF RESULTS

Negative

Only one red violet control line appears in the control line region (C). No apparent red line appears in the test line region (T). This means that no SARS-CoV-2 antigen was detected or the level of antigen in a sample is below the detection limit of the test.

Note: Nucleic acid test confirmation is recommended for negative results if the patients were suspicious of infection or with some symptoms.



Positive

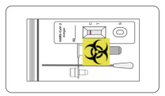
Two distinct red violet lines appear. One red violet line in the control line region (C) and the other red violet line in the test line region (T). This means that the presence of SARS-CoV-2 antigen was detected, and the patient is very likely to be infected with the virus and presumed to be contagious.

*Note: Any shade of red in the test line region (T) should be considered positive.

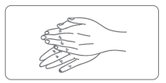
Invalid

Control line fails to appear. Insufficient specimen volume or incorrect operation is the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using a lot of kit immediately and contact your local distributor.

NOTE



After the test is completed, put all test kit materials into the biohazard bag and dispose it in trash.



After the test is completed, wash hands thoroughly (at least 20 seconds) with soap/hand sanitizer and water.

- Only use the swab provided in this kit for swab collection.
- Test specimens immediately after collection for optimal test performance. Inadequate specimen collection or improper sample handling/storage/transport may yield erroneous results. Do not return the nasal swab to the original paper packaging. Do not place the swab into transport media.
- If storage is needed for transportation, use a sterile plastic tube with cap without any transport media. Samples are stable for up to 4 hours at room temperature and up to 24 hours at 2-8°C.

DISCLAIMER

The QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test Kit does not differentiate between SARS-CoV and SARS-CoV-2. Results are for the identification of SARS-CoV-2 nucleocapsid protein antigen. This antigen is generally detectable in anterior nasal swabs during the acute phase of infection.

Persons who test positive with the QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test should self-isolate and seek follow-up care with their physician or healthcare provider as additional testing may be necessary and for public health reporting.

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 and the agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control 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. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

The QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test Kit is intended for self-use and/or, as applicable for an adult lay user testing another person aged 2 years or older in a non-laboratory setting.

SCAN TO LEARN MORE ABOUT THIS TEST AND WATCH INSTRUCION VIDEO

DIACARTA INC.
4385 HOPYARD RD, SUITE 100
PLEASANTON, CA 94588, USA

WWW.DIACARTA.COM

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INSTRUCTION FOR USE

QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test Kit

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QUANTIVIRUS™ SARS-COV-2 ANTIGEN RAPID HOME TEST KIT

Pack Size	Catalog Number	Intended Use
1-Test	DC-11-0064	• For In Vitro Diagnostic (IVD) use. • For use under the Emergency Use Authorization (EUA) only.
2-Test	DC-11-0080	
5-Test	DC-11-0065	
20-Test	DC-11-0066	

INTENDED USE

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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 and the agent detected may not be the definite cause of disease.

Negative results should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control 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. Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider.

If you have symptoms of COVID-19, you can use a single test. If you do not have symptoms of COVID-19, you will need at least two tests per person.

You may need to purchase additional tests to perform serial (repeat) testing. This test is more likely to give you a false negative result when you have COVID-19 than a lab-based molecular test.

This product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of IVDs for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. This product has not been FDA cleared or approved but has been authorized by FDA under an EUA.

STORAGE AND STABILITY

- The kit should be stored at temperatures between 2°C~30°C.
- No viral transport medium (VTM) required for storage and transportation.
- Dry and out of direct sunlight and don't freeze.
- The shelf life of test kit is 12 months. Do not use after the expiration date.
- The test cassette should be used within 60 minutes after opening the aluminumfoil pouch.

LIMITATION

- Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
- This test detects both viable (live) and non-viable, SARS-CoV, and SARS-CoV-2. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
- If the differentiation of specific SARS viruses and strains is needed, additional testing is required, in consultation with state or local public health departments, is required. The clinical performance of the test has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.
- Testing for asymptomatic individuals should be performed at least twice over three days, with at least twenty-four hours and no more than 48 hours between tests. You may need to purchase additional tests to perform this serial (repeat) testing.
- There is a higher chance of false negative results with home use tests than with laboratory-based molecular tests. This means that there is a higher chance this test will give you a negative result when you have COVID-19.
- Serial testing (i.e., testing every day or every other day) is more likely to detect COVID-19, especially when you do not have any symptoms.

PRECAUTIONS

- For in vitro diagnostic use only.
- Positive test results should be considered in the context of clinical observations and epidemiological data (such as local prevalence rates and current outbreak/epicenter locations) in making a final diagnosis and patient management decisions. Patient management should follow current CDC guidelines.
- Negative results do not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The amount of antigen in a sample may decrease as the duration of illness increases. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.
- Do not use the test if the pouch is damaged or open or even expired.
- Do not reuse any kit components, do not use with multiple specimens.
- To obtain accurate results, the test must be performed as indicated in these instructions for use.
- This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Inadequate or inappropriate sample collection may yield false test results.
- Swabs in the kit are approved for use with QuantiVirusTM SARS-CoV-2 Antigen Rapid Home Test Kit. Do not use other swabs.
- Do not use on anyone under two years of age. Keep test kit and materials out of the reach of children and pets, before and after use.
- Do not open the kit contents until ready to use. If the test cassette is open for an hour or longer, invalid test results may occur.
- Do not use the test after the expiration date shown on the test card pouch.
- 12. Make sure there is sufficient light when reading and interpreting test results.

  Do not use nasal sprays for at least 30 minutes before collecting a nasal sample.
- Remove any piercings from the nose before starting the test. Do not use on anyone who is prone to nosebleeds or has had facial injuries or head injuries/surgery in the past six months.
- Do not touch the swab head when handling the swab.
- Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature (10-30).
- The test is intended to be read at 15 -20 minutes. If the test is read before 15 minutes or after 20 minutes, false negative or false positive results may occur, and the test should be repeated with a new test card.
- Avoid exposure of your skin, eyes, nose, or mouth to the solution in the sample extraction solution.
- Do not ingest any kit components.
- The disposable kit is referred to biological waste when used.
- The sample extraction solution contains hazardous ingredients (see table below). If the solution contacts the skin or eye, flush with plenty of water. If irritation persists, seek medical advice.

Hazardous Ingredients for the Sample Extraction Solution

Chemical Name/ Concentration	Harms (GHS) code for each ingredient	Concentration
TritonX-100	Acute toxicity, Oral (Category 4), H302 Skin irritation (Category 2), H315 Serious eye damage (Category 1), H318 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	0.5%
Sodium Azide	Acute toxicity, Oral (Category 2), H300 Acute toxicity, Dermal (Category 1), H310 Specific target organ toxicity - repeated exposure, Oral (Category 2), Brain, H373 Short-term (acute) aquatic hazard (Category 1), H400 Long-term (chronic) aquatic hazard (Category 1), H410	0.05%

IF Inhalation: Move to fresh air. If not breathing, give artificial respiration. Do not use mouth-to-mouth method if victim ingested or inhaled; give artificial respiration with the aid of a pocket mask equipped with a one-way valve or other proper respiratory medical device. Immediate medical attention is required.

If Skin Contact: Take off immediately all contaminated clothing. Wash off immediately with plenty of water for at least 15 minutes. Immediate medical attention is required.

IF Eye Contact: Immediately flush eyes with plenty of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Getmedical attention immediately.

IF Ingestion: Clean mouth with water. Do not induce vomiting. Risk of aspiration! Keep airways free. Pulmonary failure possible after aspiration of vomit. Call a physician or Poison Control Center immediately.

FREQUENTLY ASKED QUESTIONS

WHAT IS ANTIGEN TESTING?

Antigen tests detect SARS-CoV-2 viral proteins and indicate that a person has an active infection. Rapid antigen tests are easy-to-use and can provide a flexible approach to detect SARS-CoV-2 in a cost-effective way.

HOW DO YOUR ANTIGEN TESTS WORK?

The QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test Kit is an antigen-capture immunochromatographic assay, detecting presence of SARS-CoV-2 viral nucleocapsid protein antigen in nasal swab specimens. This test utilizes the chemical extraction followed by solid-phase immunoassay technology for the detection of extracted antigen. Monoclonal antibodies specifically against SARS-CoV-2 viral nucleocapsid protein antigen is conjugated with colloidal gold, deposited on the conjugated pad, the gold-antibody conjugate is rehydrated and the SARS-CoV-2 nucleocapsid protein antigen, if any in the sample, will interact with the gold conjugated antibodies.

HOW ACCURATE ARE YOUR ANTIGEN TESTS?

Our data of antigen tests showed clinical sensitivity 88.2% (95% CI: 0.75.4-0.951) and specificity 100% (95% CI: 0.934-1.00). Its Positive Predictive Value (PPV) is 100% (95% CI: 0.90.2-1.00) and its Negative Predictive Value (NPV) is 92% (95% CI: 0.83-0.97).

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR THE VIRUS THAT CAUSES COVID-19?

A positive test result indicates the presence of nucleocapsid antigens from SARS-CoV-2, and the patient is infected with the virus and presumed to be contagious. Clinical correlation with patient history and other diagnostic information is necessary to determine infection status in making a final diagnostic and patient management decisions.

Persons who test positive with the QuantiVirus™ SARS-CoV-2 Antigen Rapid Home Test Kit should seek follow up care with their physician or healthcare provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses.

In the event of a false positive result, risks to patients could include the following: a recommendation for isolation of the patient, monitoring of household or other close contacts for symptoms, patient isolation that might limit contact with family or friends and may increase contact with other potentially COVID-19 patients, limits in the ability to work, the delayed diagnosis and treatment for the true infection causing the symptoms, unnecessary prescription of a treatment or therapy, or other unintended adverse effects.

WHAT DOES IT MEAN IF THE SPECIMEN TESTS POSITIVE FOR THE VIRUS THAT CAUSES COVID-19?

A negative test result means that nucleocapsid antigens from SARS-CoV-2 were not present in the specimen above the limit of detection. However, 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, including infection control 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, and confirmed with a molecular assay, if necessary, for patient management.

Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow up care with their physician or healthcare provider. Re-testing or testing with molecular methods should be considered by healthcare providers in consultation with public health authorities.

When diagnostic testing is negative, the possibility of a false negative result should be considered in the context of a patient's recent exposures and the presence of clinical signs and symptoms consistent with COVID-19. Risks to a patient of a false negative test result include delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

A negative antigen test should not be the sole basis used to determine if a patient can end isolation precautions.

DO THE ANTIGEN TESTS ALSO DETECT THE NEWLY DISCOVERED OMICRON VARIANT?

Our antigen tests are based on the detection of SARS-CoV-2 nucleocapsid proteins. Nucleocapsid proteins are much more conserved. Our antigen tests can detect Omicron N-proteins and have no impact on the performance or reliability of the antigen rapid tests.

REPORT TEST RESULT

Report the result to CDC (US Centers for Disease Control and Prevention) or share your test result with your healthcare provider.

Instruction for reporting the result to CDC could be found at https://www.diacarta.com/products/covid19/antigen-home-test.