RightSign®

COVID-19 Antigen Rapid Test Cassette (Nasal Swab) Package Insert (For Self-testing)

REF ICOVN-C81H | English

A rapid test for the qualitative detection of COVID-19 antigen in Nasal Swab in symptomatic individuals.

【INTENDED USE】

The COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasal Swab in symptomatic individuals. The identification is based on the monoclonal antibodies specific for the Nucleocapsid（N）protein of SARS-CoV-2. It is intended to aid in the rapid differential diagnosis of current COVID-19 infections.

【SUMMARY】

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. 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】

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) is a qualitative, lateral flow immunoassay for the detection of the N protein of SARS-CoV-2 in Nasal Swab. In this test, antibody specific to the N protein of SARS-CoV-2 is separately coated on the test line regions of the test cassette. During testing, the extracted specimen reacts with the antibody to N protein of SARS-CoV-2 that are coated onto particles. The mixture migrates up the membrane to react with the antibody to N protein of SARS-CoV-2 on the membrane and generate one colored line in the test regions. The presence of this colored line of the test regions indicates a positive result. To serve as a procedural control, a colored line will always appear in the control region if the test has performed properly.

【REAGENTS】

The test cassette contains anti-SARS-CoV-2 antibody, anti-SARS-CoV-2 antibody for gold conjugate, purified goat antibody, purified rabbit antibody for gold conjugate.

【PRECAUTIONS】

Please read all the information in this package insert before performing the test.

1. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use.
3. Wash hand before and after the test.
4. All specimens should be considered potentially hazardous and handled in the same manner as an infection agent.
5. The used test should be discarded according to the local regulations.
6. Avoid using bloody samples.
7. Wear disposable gloves when handling the samples, avoid touching the reagent membrane and sample well.
8. Wear a face covering when collecting nasal swab from children or others.
9. Avoid touching the swab head when handling the swab.

【STORAGE AND STABILITY】

Store as packaged at room temperature or refrigerated (2-30℃). 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.

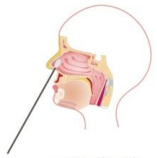
【SPECIMEN COLLECTION AND PREPARATION】

The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) can be performed using Nasal Swab specimens. The quality of specimens obtained is of extreme importance. Detection of COVID-19 Antigen requires a vigorous and thorough collection technique that provides COVID-19 Antigen rather than just body fluids.

●Nasal swab Specimen:

♦ Use the nasal swab supplied in the kit. Prior to collecting the nasal swab, blow your nose before sampling. To collect a nasal swab sample, insert the entire absorbent tip of the nasal swab (usually ⅗ to 1 of an inch (1.5 to 2.5cm)) inside the nostril and firmly sample the nasal wall by rotating the swab in a circular path against the nasal wall at least 5 times. Take approximately 15 seconds to collect the sample per nostril. Be sure to collect any nasal drainage that may be present on the swab. Sample both nostrils with the same swab before testing.

Specimen Collection Instruction



For Nasal Swab

Do not return the Nasal swab to the original paper packaging.

♦ For best performance, direct Nasal swabs should be tested as soon as possible after collection.

【MATERIALS】

Materials provided	Quantity (Piece)			
	1T	2T	5T	25T
Test Cassette	1	2	5	25
Prefilled buffer vials	1	2	5	25
Sterile Nasal Swab	1	2	5	25
Disposal Bag	1	2	5	25
Quick Reference Guide	1	1	1	1
Workstation	/	/	/	1
Package insert	1	1	1	1

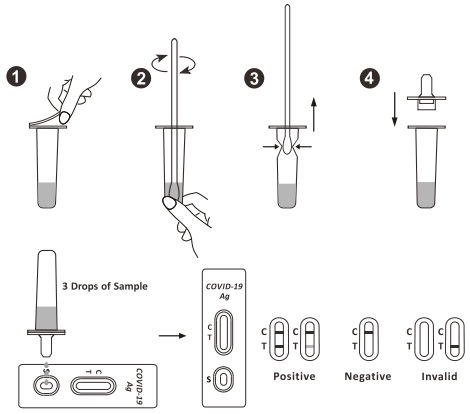
Materials required but not provided

• Timer

【DIRECTIONS FOR USE】

Allow the test, specimen, extraction buffer to equilibrate to room temperature (15-30℃) prior to testing.

1. Wash your hand before starting your test. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Tear the aluminum foil on the prefilled buffer . See illustration 1.
3. Place the swab specimen in the prefilled buffer. Rotate the swab for approximately 10 seconds while pressing the head against the inside of the prefilled buffer vial body to release the antigen in the swab. See illustration 2.
4. Remove the swab while squeezing the swab head against the inside of the individual vial as you remove it to expel as much liquid as possible from the swab. Dispose of the swab according to the local biohazardous waste disposal protocol. See illustration 3.
5. Fit the dropper tip on top of the prefilled buffer vial. Place the test cassette on a clean and flat surface. Do not move the test cassette during the test. See illustration 4.
6. Hold the dropper vertically and transfer 3 drops of the sample solution (approx.80μL) to the sample well and then start the timer. Read the result at 10 minutes. Do not interpret the result after 20 minutes.
7. Please dispose off the swab, buffer vial and test cassette in the disposal bag provided inside the test kit package. Wash your hands after the test.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that COVID-19 was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of COVID-19 Antigen present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that COVID-19 antigen is not present in the specimen, or is present below the detectable level of the test.

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 or manufacturer for technical support:

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+86-571-89058051 (North America/Latin America)
E-mail : info.support@biotests.com.cn
Website: www.biotests.com.cn.

【LIMITATIONS】

1. The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) should be used for the detection of COVID-19 Antigen in Nasal Swab. Neither the quantitative value nor the rate of increase in SARS-CoV-2 virus concentration can be determined by this qualitative test.
2. The accuracy of the test depends on the quality of the Nasal Swab sample. False negatives may result from improper sample collection or storage.
3. The COVID-19 Antigen Rapid Test Cassette (Nasal Swab) will only indicate the presence of SARS-CoV-2 in the specimen from both viable and non-viable SARS-CoV-2 coronavirus strains.
4. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
5. Concentration of the SARS-CoV-2 virus are generally lower at the early and the later stage of the infection. A negative result may be obtained if the concentration of the SARS-CoV-2 virus present in the nasal swab is not adequate or is below the detectable level of the test. A negative result obtained from this kit should be confirmed by PCR. A PCR Test after 24 hours or 3 Consecutive tests at in interval of 24 hours each by a COVID-19 Antigen test are recommended.
6. Excess blood or mucus on the specimen may interfere with test performance and may yield a false positive result.
7. A positive result for COVID-19 does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.
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 and continue self-isolating at home at least 14 days should be considered to rule out infection in these individuals.
9. There exists a very small probability of a false positive results to be encountered due to presence of non-SARS-COV-2 coronavirus strains such as coronavirus HKU1, NL63, OC43 or 229E. Tests have been carried out for these respiratory pathogens at a certain high level to exclude the possibility of false results due to their presence at moderate levels. However, a false result due to presence of these pathogens at levels higher than tested cannot be ruled out.
10. Results from antigen testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.
11. Extraction buffer can only inactivate the virus to a limited extent and cannot be used as an anti-virus agent for treating the waste before disposal. All materials including the extraction buffer used in the testing should be considered potentially infectious and should be disposed off in the disposal bag provided with the test as a biohazards waste.
12. The performance of the COVID -19 Antigen Rapid Test Cassette (Nasal Swab) was determined based on the evaluation of a limited number of clinical specimens. Clinical performance was not determined for all circulating variants, but is considered to reflect the variants prevalent at the time and site of clinical evaluation. Performance at the time of testing may vary depending on circulating variants, including emerging strains of SARS-CoV-2 and their prevalence, which change over time.

【EXTRA INFORMATIONS】

1. Who this test is suitable for?

Age 18 and above can complete the test independently. Adolescents aged 13-17 can complete the test with the help of an adult. Children under 13 years should be tested by an adult. The study has been performed with minimum age group of 3-13 years of age. No study has been performed on children of less than 3 years of age. So use of this test for children below 3 years of age is not

recommended. Discontinue testing if sampling children is difficult.

2. How does the test cassette work?

The COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is a rapid chromatographic immunoassay for the qualitative detection of COVID-19 antigen in Nasal Swab. It is intended to aid in the rapid differential diagnosis of COVID-19 infections.

3. How accurate is the test?

A clinical evaluation was conducted comparing the results obtained using the COVID-19 Antigen Rapid Test Cassette(Nasal Swab) to PCR. Specimens were considered positive if PCR indicated a positive result.

For 103 cases of PCR positive，the relative sensitivity the COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is 93.2%(96/103).

For 250 cases of PCR negative，the relative specificity of COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is 99.2%(248/250).

For 103 cases of PCR positive and 250 cases of PCR negative ,the Relative accuracy of COVID-19 Antigen Rapid Test Cassette(Nasal Swab) is 97.5%(344/353).

4. Will other diseases affect the result?

No cross reactivity has been observed on testing by following commonly found respiratory/ oropharyngeal pathogens - Influenza A virus, Influenza B virus, Adenovirus, Coxsackie virus, Parainfluenza Virus Type1, Parainfluenza Virus Type2, Parainfluenza Virus Type3, Parainfluenza Virus Type4a, Enterovirus, Mumps virus, Respiratory syncytial virus, Rhinovirus, Bordetella pertussis, Haemophilus parainfluenzae, Staphylococcus aureus, Streptococcus agalactiae, Neisseria meningitides, Streptococcus sp. group A, Streptococcus sp. group B, Streptococcus sp. group C, Candida albicans, Human Metapneumovirus (hMPV), Legionella pneumophila, Mycobacterium tuberculosis, Mycoplasma pneumoniae, Pneumocystis jirovecii(PJP)-S cerevisiae Recombinant, Pseudomonas aeruginosa, Staphylococcus epidermis, Streptococcus pneumoniae, Streptococcus pyogenes, Streptococcus salivarius, Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, MERS-coronavirus positive specimens. However, a false result due to presence of these organisms at a level higher than tested cannot be ruled out.

5. Will this test hurt?

No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable or tickly. If you feel pain, please stop the test and seek advice from a healthcare provider.

6. I have a nosebleed after swabbing my nose. What should I do?

In the unlikely event your nose starts bleeding, apply pressure to your nose until the bleeding stops and consult a healthcare professional. Do not insert the Swab again.

7. How do I know that the test was run properly?

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

8. What should I do if the result shows positive?

Please consult immediately with a qualified healthcare provider and inform the immediate contacts you have had in past 24 hours. Actions should be taken according to local guidelines to limit further spread of the infection. Immediate PCR Testing is advised and self-isolation and any medical treatment should be based on PCR Testing. A lab-based test by PCR method is recommended to confirm a positive result.

9. What should I do if the result shows negative?

Negative results may require additional testing to confirm your result. Please talk to your healthcare provider to determine if you need additional testing. It is likely that you were not infectious at the time the test was taken. A negative test result, however, is not a guarantee that you do not have coronavirus. Please continue to follow social distancing and local regulations.

10. Can RightSign COVID-19 Antigen Test detect various variants of COVID-19?

Yes, the test can detect different variants. A detailed list is available on request.

【BIBLIOGRAPHY】

1. Weiss SR, Leibowitz JL. Coronavirus pathogenesis. Adv Virus Res 2011;81:85-164.
2. Cui J, Li F, Shi ZL. Origin and evolution of pathogenic coronaviruses. Nat Rev Microbiol 2019;17:181-192.
3. Su S, Wong G, Shi W, et al. Epidemiology, genetic recombination, and pathogenesis of coronaviruses. TrendsMicrobiol 2016;24:490-502.

Index of Symbols

	Consult Instructionfor use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Keep away from sunlight		Keep dry

Manufacturer
Hangzhou Biotest Biotech Co., Ltd.
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Yuhang District, Hangzhou, P.R. China

CE 1434

EC REP
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