aichek

IVD CE 2934

COVID-19 Antigen Home Test Instructions for Use

English

For self-testing and in vitro diagnostic use only.

INTENDED USE

The COVID-19 Antigen Home Test is a lateral flow chromatographic immunoassay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in anterior nasal swab specimens directly from individuals within 7 days of symptom onset to suspect COVID-19 infection, not intended for asymptomatic users.

The COVID-19 Antigen Home Test is intended for self-use or lay person testing another in a non-laboratory setting. The reagent is suitable for use by adults between 18 and 75 years of age. For child and adolescent ages 18 years or younger and for people over 75 years of age, use only under the supervision and assistance of authorized persons. Not to be performed on children under 2 years of age.

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 Home Test is a qualitative membrane based chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human anterior nasal swab specimens.

When specimens are processed and added to the test cassette, SARS-CoV-2 antigens, if present in the specimen, will react with the colored anti-SARS-CoV-2 antibody-coated particles, which have been precoated on the test strip. The antigen-antibody complex then migrates towards the membrane by capillary action. This complex is then captured by anti-SARS-CoV-2 monoclonal antibody immobilized at the test line region, and a colored line appears on the membrane. Test results are interpreted visually at 15~20 minutes based on the presence of the absence of visually colored lines.

To serve as a procedure control, a red line will always appear in the control line region after proper volume of specimen has been added, and membrane wicking has occurred.

PRECAUTIONS

• Read the COVID-19 Antigen Home Test instruction for use carefully before performing a test. Follow directions for use. Failure to follow directions may produce inaccurate test results.

• For in vitro diagnostic use only.

• Do not use after the expiration date. Do not use the test if the pouch is damaged or open. Do not reuse any kit components. Do not use with multiple specimens.

• Do not dismantle and touch the test window of the test cassette.

• Make sure there is sufficient light when reading and interpreting test results.

• Do not use nasal sprays for at least 20 minutes before collecting a nasal sample.

• Do not touch the swab head when handling the swab.

• Avoid exposure of your skin, eyes, nose, or mouth to the solution in the extraction tube.

• Keep test kit and materials out of the reach of children and pets, before and after use. Do not eat any kit components.

• 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.

• 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.

• 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 cassette.

• Inadequate or inappropriate sample collection may yield false test result.

• Invalid results, indicated by no Control Line, can occur when an insufficient volume of sample solution is added to the test cassette. Gently squeeze the tube and dispense 3 drops of solution into the sample well of test device.

• You'd better use the reagent to hold a test at the temperature 2~30°C.

• The test results of this test kit are for preliminary screening and clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the user's clinical manifestations and other laboratory tests.

COMPONENTS

Package Specification

Package Specification	Cat. No.
1 test/pouch	COVID-19-G02001B
1 test/kit	COVID-19-G02001A
5 test/kit	COVID-19-G02005A
20 test/kit	COVID-19-G02020A

Materials Provided

• Test Cassette(s)

• Extraction tube(s) with extraction buffer

• Instructions for use

• Waste bag(s)

• Disposable Nasal Swab(s)

Manufacturer information of Disposable Nasal Swab:	
	Jiangsu Rongye Technology CO., Ltd.Touqiao Town, Yangzhou City, Jiangsu Province, China
EC REP	Riomavix S.L.Calle de Almansa 55, 1D, Madrid 28039 Spain
CE mark	CE 0197
Method of Sterilization	STERILE EO

Materials Required But Not Provided

• Timer

STORAGE AND STABILITY

Store as packaged in the sealed pouch at the temperature (2~30°C or 36~86°F).

The shelf life of the product is 15 months. The kit is stable within the expiration date printed on the labeling. DO NOT FREEZE.

The LOT and the expiration date were printed on the labeling.

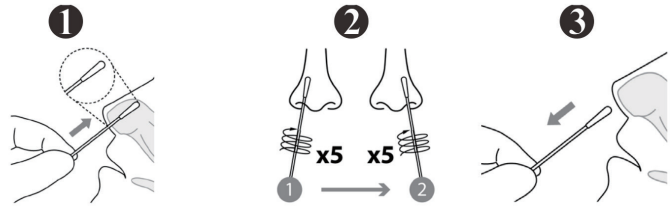
Please use as soon as possible after opening the bag.

SPECIMEN COLLECTION AND PREPARATION

• The COVID-19 Antigen Home Test is performed using anterior nasal swab specimens.

• Wash or sanitize your hands. Make sure they are dry before starting the test.

• To collect an anterior nasal swab specimen:



1. Gently insert the entire absorbent tip of the swab head into 1 nostril (1.3 cm~1.9 cm). With children, the maximum depth of insertion into the nostril may be less than1.9 cm, and you may need to have a second person to hold the child's head while swabbing.

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

2. 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. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril using the same swab.

3. Remove the swab from the nostril and place into the extraction buffer tube.

INSTRUCTION

1.Tear the sealing from the top of the extraction buffer tube.

2.Insert the swab into the tube until the liquid immersed the swab head, squeeze10~15 times.

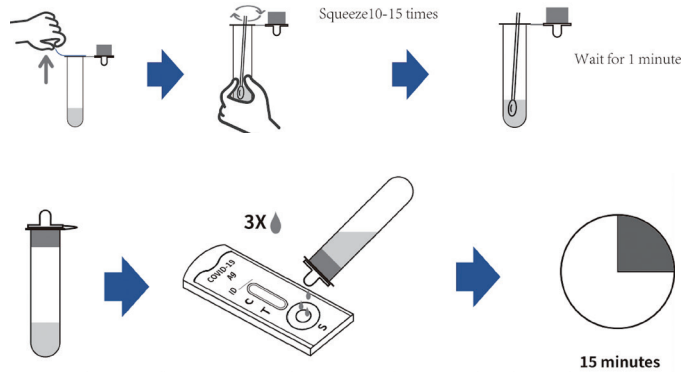
3.Wait for 1 minute, then discard the swab.

4.Take the test device from the packaging bag, place it on the table.

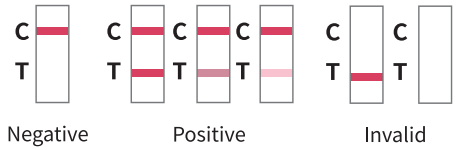
5.Attach the dropper tip firmly onto the tube, invert the tube and add 3 drops of the sample mixer into the sample hole vertically. Do not to move or lift the test cassette while the test is being performed.

6.Set the timer for 15 minutes. Result should be read at 15~20 minutes in a well lighted area. Do not read after 20 minutes.

7.After the test is completed, place all the components into the waste bag (supplied). Dispose according to local regulation. Wash your hands after test.



READING THE RESULTS



POSITIVE RESULT: Two colored bands appear on the membrane. One bland appears in the control region (C) and another band appears in the test region (T). Therefore, any shade of color in the test line region (T) should be considered positive. 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. Test results should always 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.

NAGATIVE RESULT: Only one colored band appears in the control region (C). No apparent colored band appears in the test region (T). This means that no SARS-CoV-2 antigen was detected. However, a negative result does 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.

INVALID RESULT: Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

QUALITY CONTROL

A procedural control is included in the test. A colored line appearing in the control region (C) is considered an internal procedural control. The appearance of the procedural control line indicates that proper volume of specimen has been added and capillary flow occurred. If the procedural control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new cassette is recommended.

LIMITATIONS

1. The COVID-19 Antigen Home Test is for in vitro diagnostic use only. The test should be used for anterior nasal swab specimens. The intensity of the test line does not necessarily correlate to SARS-CoV-2 viral titer in the specimen.

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.

3. Test results should be correlated with other clinical data available to the physician.

4. A positive or negative test result does not rule out co-infections with other pathogens such as other viral or bacterial infections.

5.Negative results are presumptive, do not rule out COVID-19 infection and it may be necessary to obtain additional testing with a molecular assay, if needed for patient management.

6.A false negative result may occur if the level of antigen in a sample is below the detection limit of the test.

7.Incorrectly sample collected and handled, may cause a false negative result.

8.Please make sure that a proper amount of sample is added for testing. Too much or too little sample may cause deviations in results.

9.The test device is a disposable product. Please dispose properly after use.

10.The amount of antigen in a sample may decrease as the duration of illness increases.

11. The test kit is used for rapid detection of suspected COVID-19 cases within the first 7 days of symptom onset, so asymptomatic individuals may get a false-negative test result.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted by the results of the test reagent and RT-PCR. 565 individuals were collected specimen with an anterior nasal swab (used for antigen test) and a nasopharyngeal swab (used for RT-PCR test) from the same subject.115 were positive and 450 were negative according to RT-PCR result. Base on the results from the clinical studies, the statistical analysis was made as follows:

		RT-PCR		Total
		Positive	Negative	
Aichek COVID-19 Antigen Test	Positive	106	3	109
	Negative	9	447	456
Total		115	450	565

Clinical sensitivity: 92.17% (95% CI: 85.79%～95.83%)

Clinical specificity: 99.33% (95% CI: 98.06%～99.77%)

Total Coincidence rate: 97.88% (95% CI: 96.32%～98.78%)

Note: Clinical sensitivity means the coincide rate of antigen test result and the PCR result by testing positive samples; Clinical specificity means the coincide rate of antigen test result and the PCR result by testing negative samples; Total Coincidence rate means the total coincide rate of antigen test result and the PCR result by testing positive and negative samples.

Ct Value	RT- PCR Positive	Antigen Test Positive	Sensitivity
Ct - Wert≤20	12	12	100.00%
Ct - Wert≤ 25	67	67	100.00%
Ct - Wert≤ 30	112	105	93.75%
Ct - Wert≤ 35	115	106	92.17%

Limited of Detection (Analytical Sensitivity)

The detection limit of the product to SARS-CoV-2 is 50 $TCID_{50}$/ mL.

Hook Effect

No high dose hook effect was observed when tested with up to a concentration of $10^7 TCID_{50}$/mL of heat-inactivated SARS-CoV-2 virus with the COVID-19 Antigen Home Test.

Analytical Specificity: Cross-reactivity and Interference

1.Cross-reactivity of the device was evaluated by testing, related pathogens and microorganisms that are likely to be present in the nasal cavity. Each organism and virus were tested in the absence or presence of SARS-CoV-2 virus at a low concentration. No cross-reactivity was observed with the following organisms presented in the table below.

Microorganisms	Cross-reactivity Results
Human coronavirus HKU1	No Cross-reactivity
Human coronavirus OC43	No Cross-reactivity
Human coronavirus NL63	No Cross-reactivity
Human coronavirus 229E	No Cross-reactivity
MERS-coronavirus	No Cross-reactivity
Influenza A H1N1	No Cross-reactivity
Influenza B Colorado/6/17	No Cross-reactivity
Rhinovirus 1A	No Cross-reactivity
Adenovirus 1	No Cross-reactivity
Enterovirus Type 68 Major Group	No Cross-reactivity
Metapneumovirus	No Cross-reactivity
Parainfluenza virus 1	No Cross-reactivity
Respiratory syncytial virus	No Cross-reactivity
Mycoplasma pneumonia	No Cross-reactivity
Chlamydia pneumonia	No Cross-reactivity
Streptococcus pneumonia	No Cross-reactivity
Staphylococcus aureus	No Cross-reactivity
Mycobacterium tuberculosis	No Cross-reactivity
Haemophilus influenzae	No Cross-reactivity
Streptococcus pyogenes	No Cross-reactivity
SARS-coronavirus	No Cross-reactivity
Rotavirus	No Cross-reactivity
Parainfluenza virus 2	No Cross-reactivity
Parainfluenza virus 3	No Cross-reactivity
Parainfluenza virus 4A	No Cross-reactivity
Influenza A H3N2 TFexas/50/12	No Cross-reactivity
Influenza B Utah/9/14	No Cross-reactivity
Candida albicans	No Cross-reactivity
Bordetella pertussis	No Cross-reactivity
Legionella pneumophila	No Cross-reactivity
Staphylococcus epidermidis	No Cross-reactivity
Influenza A H1N1pdm California/07/2009	No Cross-reactivity
Influenza B Washington/02/19	No Cross-reactivity

2. Some potential interfering substances were spiked into the absence or presence of SARS-CoV-2 virus at a low concentration and tested by the device. No interference was observed listed in the table below.

Substances	Interference Results
Biotin	No Interference
Mucin	No Interference
HAMA Serum	No Interference
Whole Blood	No Interference
Nasal Spray (Budesonide)	No Interference
Nasal Spray (Oxymetazoline Hydrochloride)	No Interference
Nasal Spray (Fluticasone Propionate)	No Interference
Tobramycin	No Interference
Mupirocin	No Interference
Mouthwash	No Interference
Ofloxacin	No Interference
Oseltamivir	No Interference
Ceftriaxone	No Interference
Chloraseptic	No Interference
Sore Throat Phenol	No Interference
Fluticasone	No Interference
Zicam	No Interference

INDEX OF SYMBOL

	Do not reuse	IVD	In vitro diagnostic medical device
2℃ 30℃	Temperature limit 2-30℃		Consult instructions for use
	Caution	LOT	Batch Code
	Use by date	Σ	Number of tests
	Keep away from sunlight		Keep dry
	Manufacturer		Do not use if package is damaged
REF	Catalogue number		Biological risks
EC REP	Authorized representative in the European Community		
CE 2934	CE mark		

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