SCREEN

CHECK TEST

Screen Covid-19 Antigen Test

SARS-CoV-2 Antigen Rapid Test
(Nasal Swab)
Package Insert

REF: 983192143	**English**
CATALOGUE NR: INCP-502H	**English**

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein antigens present in nasal swab specimen. For self-testing *in vitro* diagnostic use.

INTENDED USE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a single-use test kit intended to detect the SARS-CoV-2 that causes COVID-19 with self-collected nasal swab specimen. The test is intended for use in symptomatic individuals meeting the case definition for COVID-19, and to test asymptomatic individuals limited to contacts of confirmed COVID-19 cases or probable cases and to at-risk health workers.

Results are for the detection of SARS-CoV-2 Nucleocapsid protein Antigens. 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 are indicative of the presence of SARS-CoV-2. Individuals who test positive should self-isolate and seek additional care from their healthcare provider. Positive results do not rule out bacterial infection or co-infection with other viruses. Negative results do not preclude SARS-CoV-2 infection. Individuals who test negative and continue to experience COVID-like symptoms should seek follow up care from their healthcare provider.

SUMMARY

The novel coronaviruses belong to the ß 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.[1]

PRINCIPLE

The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 nucleocapsid protein antigens in human swab specimen.

PRECAUTIONS

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

- For self-testing *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Store in a dry place at 2-30 °C (36-86 °F), avoiding areas of excess moisture. If the foil packaging is damaged or has been opened, please do not use.
- This test kit is intended to be used as a preliminary test only and repeatedly abnormal results should be discussed with doctor or medical professional.
- Follow the indicated time strictly.
- Use the test only once. Do not dismantle and touch the test window of the test cassette.
- The kit must not be frozen or used after the expiration date printed on the package.
- Wash hands thoroughly after handling.
- Please ensure that an appropriate amount of samples are used for testing. Too much or too little sample size may lead to deviation of results.
- **Do not drink the buffer in the kit.** Carefully handle the buffer and avoid it contacting skin or eyes, rinse with plenty of running water immediately if contacting.
- Test for children and young people should be used with an adult.

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.

MATERIALS

Material Provided

- Test cassette
- Sterile swab
- Package insert
- Extraction buffer
- Biosafety bag

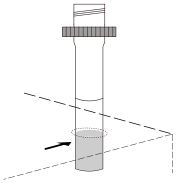
Materials required but not provided

- Timer

PROCEDURE

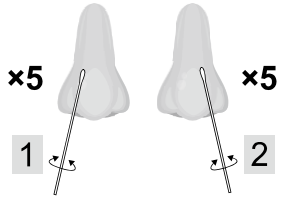
Wash your hands with soap and water for at least 20 seconds before and after test. If soap and water are not available, use hand sanitizer with at least 60% alcohol.

Remove the cover of the tube with Extraction buffer and place the tube in the tube holder in the box.



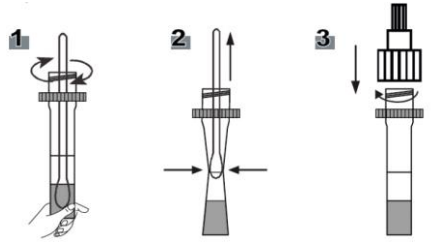
Nasal swab specimen Collection

1. Remove the sterile swab from the pouch.
2. Insert the swab into your nostril until you feel slight resistance (Approx. 2cm up your nose). Slowly twist the swab, rubbing it along the insides of your nostril for 5-10 times against the nasal wall.
   Note: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain. When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended. If you are swabbing others, please wear a face mask. With children, you may not need to insert the swab as far into the nostril. For very young children, you may need another person to steady the child's head while swabbing.
3. Gently remove the swab.
4. Using the same swab, repeat step 2 in your other nostril.
5. Withdraw the sterile swab.



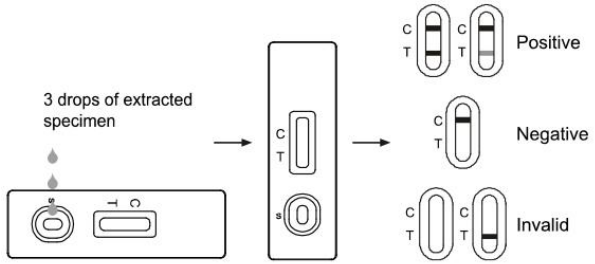
Specimen Preparation

1. Place the swab into the Extraction tube, ensure it is touching the bottom and stir the swab to mix well. Press the swab head against to the tube and rotate the swab for **10-15 seconds**.
2. Remove the swab while squeezing the swab head against the inside of the Extraction tube. Place the swab in the biosafety bag.
3. Close the cap of the extraction tube.



Testing

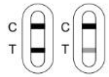
1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch. Place the test cassette on a plat and level surface.
2. Open the small cap and Invert the specimen extraction tube and add **3 drops of extracted specimen** to the sample well(S) of the test cassette and start the timer. Do not move the test cassette during test developing.
3. **Read the result at 15 minutes.** Do not read the result after 20 minutes.



Note: After test is completed, place all the components into plastic Biosafety Bag and dispose according to local regulation.

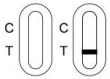
READING THE RESULTS

Please share your test result with your healthcare provider and carefully follow your local COVID guidelines/requirements.



POSITIVE:* Two colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Test region (T).
***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. A positive results means it is very likely you have COVID-19, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps .

NEGATIVE: One colored line appears in the control region (C). No line appears in the test line region (T).
You are unlikely to have COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection. Even with a negative test result, distance and hygiene rules must be observed, mitigation traveling, attending events and etc. should follow your local COVID guidelines/requirements.



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 or contact with a COVID-19 test center.

LIMITATIONS

1. Performance was evaluated with nasal swab specimens only, usingthe procedures provided in this package insert.
2. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) will only indicate the presence of SARS-CoV-2 antigens in the specimen.
3. If the test result is negative or non-reactive and clinical symptoms persist, it is because the very early infection virus may not be detected, It is recommended to test again with a new kit or test with a molecular diagnostic device to rule out infection in these individuals.
4. 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.
5. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
6. Failure to follow these procedures may alter test performance.
7. False negative results may occur if a specimen is improperly collected or handled.
8. False negative results may occur if inadequate levels of viruses are present in the specimen.

PERFORMANCE CHARACTERISTICS

Clinical performance

The SARS-CoV-2 Antigen Rapid Test was evaluated with clinical nasal swab specimens whose status was confirmed using RT-PCR(Nasopharyngeal Swab). The sensitivity was calculated for the range from high to low viral load. The results are presented in the following tables.

A clinical evaluation was conducted comparing the results obtained using the SARS-CoV-2 Antigen Rapid Test with RT-PCR test result.

The clinical trial included 847 nasal swab specimens. The results demonstrated 99.4% specificity and 95.4% sensitivity with an overall accuracy of 97.8%.

		RT-PCR, Ct≤25	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	261	3
	Negative	0	611
	Total	261	614

Diagnostic sensitivity (Ct≤25): 100% (98.9%-100%)*
Overall agreement (Ct≤25): 99.7% (99.0% - 99.9%)*
Diagnostic specificity: 99.5% (98.6% - 99.9%)*

		RT-PCR, Ct≤30	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	335	3
	Negative	1	611
	Total	336	614

Diagnostic sensitivity (Ct≤30): 99.7% (98.4% - 99.9%)*
Overall agreement (Ct≤30): 99.6% (98.9% - 99.9%)*
Diagnostic specificity: 99.5% (98.6% - 99.9%)*

		RT-PCR, Ct≤33	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	381	3
	Negative	4	611
	Total	385	614

Diagnostic sensitivity (Ct≤33): 99.0% (97.4% - 99.7%)*
Overall agreement (Ct≤33): 99.3% (98.6% - 99.7%)*
Diagnostic specificity: 99.5% (98.6% - 99.9%)*

		RT-PCR, Ct < 36	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	423	3
	Negative	12	611
	Total	435	614

Diagnostic sensitivity (Ct < 36): 97.2% (95.2% - 98.6%)*

Overall agreement (Ct < 36): 98.6% (97.7% - 99.2%)*

Diagnostic specificity: 99.5% (98.6% - 99.9%)*

Note: There are 12 specimens with very low viral load(Ct≥36), 8 of them were correctly identified.

The SARS-CoV-2 Antigen Rapid Test was evaluated with clinical nasal swab specimens from asymptomatic individuals whose status was confirmed using RT-PCR(Nasopharyngeal Swab). The sensitivity was calculated for the range from high to low viral load. The results are presented in the following tables.

		RT-PCR, Ct≤25	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	20	1
	Negative	0	99
	Total	20	100

Diagnostic sensitivity (Ct≤25): 100% (86.1% - 100%)*
Overall agreement (Ct≤25): 99.2% (95.4% - 100%)*
Diagnostic specificity: 99.0% (94.6% - 100%)*

		RT-PCR, Ct≤30	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	64	1
	Negative	0	99
	Total	64	100

Diagnostic sensitivity (Ct≤30): 100% (95.4% - 100%)*
Overall agreement (Ct≤30): 99.4% (96.6% - 100%)*
Diagnostic specificity: 99.0% (94.6% - 100%)*

		RT-PCR, Ct≤33	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	75	1
	Negative	0	99
	Total	75	100

Diagnostic sensitivity (Ct≤33): 100% (96.1% - 100%)*
Overall agreement (Ct≤33): 99.4% (96.9% - 100%)*
Diagnostic specificity: 99.0% (94.6% - 100%)*

		RT-PCR, Ct≤38	
		Positive	Negative
SARS-CoV-2 Antigen Rapid Test	Positive	87	1
	Negative	2	99
	Total	89	100

Diagnostic sensitivity (Ct≤38): 97.8% (92.1% - 99.7%)*
Overall agreement (Ct≤38): 98.4% (95.4% - 99.7%)*
Diagnostic specificity: 99.0% (94.6% - 100%)*
*95% confidence interval

Cross-reactivity

Test results will not be affected by other respiratory viruses and commonly encountered microbial flora and low pathogenic coronaviruses listed in table below at certain concentrations.

Description	Test Level
Human coronavirus 229E	5x 10^5 $TCID_{50}$/mL
Human coronavirus NL63	1x 10^6 $TCID_{50}$/mL
Human coronavirus OC43	1 x 10^6 $TCID_{50}$/mL
MERS coronavirus Florida	1.17x10^4 $TCID_{50}$/mL
Human coronavirus HKU1	1x 10^6 $TCID_{50}$/mL
Influenza A H1N1	3.16 x 10^5 $TCID_{50}$/mL
Influenza A H3N2	1 x 10^5 $TCID_{50}$/mL
Influenza B	3.16 x 10^6 $TCID_{50}$/mL
Parainfluenza virus 2	1.58 x 10^7 $TCID_{50}$/mL
Parainfluenza virus 3	1.58 x 10^8 $TCID_{50}$/mL
Respiratory syncytial virus	8.89 x 10^4 $TCID_{50}$/mL
Adenovirus type 3	3.16 x 10^4 $TCID_{50}$/mL
Adenovirus type 7	1.58 x 10^5 $TCID_{50}$/mL
Human Rhinovirus 2	2.81 x 10^4 $TCID_{50}$/mL
Human Rhinovirus 14	1.58 x 10^6 $TCID_{50}$/mL
Human Rhinovirus 16	8.89 x 10^6 $TCID_{50}$/mL
Measles	1.58 x 10^4 $TCID_{50}$/mL
Mumps	1.58 x 10^4 $TCID_{50}$/mL
Arcanobacterium	1.0x10^8 org/mL
Candida albicans	1.0x10^8 org/mL
Corynebacterium	1.0x10^8 org/mL
Escherichia coli	1.0x10^8org/mL
Moraxella catarrhalis	1.0x10^8 org/mL
Neisseria lactamica	1.0x10^8 org/mL
Neisseria subflava	1.0x10^8 org/mL
Pseudomonas aeruginosa	1.0x10^8 org/mL
Staphylococcus aureus subspaureus	1.0x10^8org/mL
Staphylococcus epidermidis	1.0x10^8 org/mL
Streptococcus pneumoniae	1.0x10^8 org/mL
Streptococcus pyogenes	1.0x10^8 org/mL
Streptococcus salivarius	1.0x10^8 org/mL
Streptococcus sp group F	1.0x10^8 org/mL

Interfering Substances

Test results will not be interfered by following substances at certain concentrations:

Substance	Concentration	Substance	Concentration
Whole Blood	20µl/mL	Oxymetazoline	0.6mg/mL
Mucin	50µg/mL	Phenylephrine	12mg/mL
Budesonide Nasal Spray	200µl/mL	Rebetol	4.5µg/mL
Dexamethasone	0.8mg/mL	Relenza	282ng/mL
Flunisolide	6.8ng/mL	Tamiflu	1.1µg/mL
Mupirocin	12mg/mL	Tobramycin	2.43mg/mL

EXTRA INFORMATIONS

1. How does the SARS-CoV-2 Antigen Rapid Test work?

The test is for the qualitative detection of SARS-CoV-2 antigens in selfcollected swab specimens. A positive result indicates SARS-CoV-2 antigens present in the specimen.

2. When should the test be used?

SARS-CoV-2 antigen can be detected in acute respiratory tract infection, it is recommended to run the test in symptomatic individuals meeting the case definition for COVID-19 (•Acute onset of fever, cough; or •Acute onset of ANY THREE OR MORE of the following signs or symptoms: Fever, cough, general weakness/fatigue, headache, myalgia, sore throat, coryza, dyspnoea, anorexia/nausea/vomiting, diarrhoea, altered mental status.), and to test asymptomatic individuals limited to contacts of confirmed COVID-19 cases or probable cases and to at-risk health workers.

3. Can the result be incorrect?

The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if inadequate sampling volume or the SARS-CoV-2 Antigen Rapid Test gets wet before test performing, or if the number of extraction buffer drops are less than 3 or more than 4. Besides, due to immunological principles involved, there exist the chances of false results in rare cases. A consultation with the doctor is always recommended for such tests based on immunological principles.

4. How to interpret the test if the color and the intensity of the lines are different?

The color and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the color intensity of the test line is.

5. What do I have to do if the result is negative?

A negative result means that you are negative or that the viral load is too low to be recognized by the test. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative. In addition, you can repeat the test with a new test kit. In case of suspicion, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection. Distance and hygiene rules must still be observed. Even with a negative test result, distance and hygiene rules must be observed, mitigation/traveling, attending events and etc. should follow your local COVID guidelines/requirements.

6. What do I have to do if the result is positive?

A positive result means the presence of SARS-CoV-2 antigens. A positive results means it is very likely you have COVID-19. Immediately go into self isolation in accordance with the local guidelines and immediately contact your general practitioner / doctor or the local health department in accordance with the instructions of your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.

BIBLIOGRAPHY

1. Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia (Trial Version 7). National Health Commission & National Administration of Traditional Chinese Medicine.2020

INDEX OF SYMBOLS

	Consult Instructions For Use		Tests per kit		Authorized Representative
	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C		Lot Number		Catalog #
	Do not use if package is damaged		Manufacturer		

Hangzhou AllTest Biotech Co.,Ltd.
#550,Yinhai Street
Hangzhou Economic & Technological Development Area
Hangzhou, 310018 P.R. China
Web: www.alltests.com.cn Email: info@alltests.com.cn

CE 1434

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Distributed by:
Screen Italia Srl
Via dell'Artigianato, 16
06089 - Torgiano - Perugia - Italia
www.screenpharma.it - info@screenpharma.it

Statement: Information about manufacturer of sterile swab is placed on the swab packaging

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