ALL TEST INCP-502H Home Use Rapid Test User Guide

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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 from symptomatic individuals who are suspected of being infected with COVID-19 within the first 7 days of symptom onset. 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 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. do not rule out bacterial infection or co-infection with other viruses. Negative results do not The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is intended to be used by laypersons as a self-test for home and workplace (in offices, for sporting events, airports, schools, etc.).

Contents

SUMMARY

The novel coronaviruses belong to the 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 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.
- 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.
- 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.
- Keep out of the reach of children.
- Test for children and young people should be used with an adult. Do not use the test on children under 2 years old.
- Small children should be swabbed with the help of a second adult. Wash hands thoroughly before and 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.

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 PROVIDED

- Test cassette
- Package insert
- Sterile swab
- Extraction buffer
- Biosafety bag
- Materials required but not provided
- Timing device

LIMITATIONS

1. Performance was evaluated with nasal swab specimens only, using the 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.
9. The SARS-CoV-2 Antigen Rapid Test (Nasal Swab) is less reliable in the later phase of infection, it is recommended to use the test within the first 7 days of symptom onset.

PERFORMANCE CHARACTERISTICS

Clinical performance

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 841 nasal swab specimens. The results demonstrated 99.4% specificity and 95.9% sensitivity with an overall accuracy of 98.0%.

	PCR confirmedsample number	Correctidentified	Rate
Positive sample	341	327	95.9%(Sensitivity)
Negative sample	500	497	99.4%(Specificity)
Total	841	824	98.0%(Total Accuracy)

95.9% Sensitivity: In total 341 PCR confirmed positive samples: 327 PCR confirmed positive samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There are 14 false negative cases. 99.4% Specificity: In total 500 PCR confirmed negative samples: 497 PCR confirmed negative samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. There are only 3 false positive cases. 98.0% Accuracy: In total 841 PCR confirmed samples: 824 PCR confirmed samples were correctly detected by SARS-CoV-2 Antigen Rapid Test. The observed accuracy may vary depending on the prevalence of the virus in the population. The observed accuracy may vary depending on the prevalence of the virus in the population

		SARS-CoV-2	
Days since	**RT-PCR**		
symptom onset	**positive**	**Antigen Rapid**	**PPA**
		Test Positive	
0-3	270	262	97.0%
4-7	71	65	91.5%

Specificity Testing with Various Viral Strains
The 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:
Adenovirus type 3 (3.16×10 TCIDs/ml), Adenovirus type 7 (1.58×105 TCID/ml), Human coronavirus OC43 (1×10 TCIDs/ml), Human coronavirus 229E (5×10 TCID/ml), Human coronavirus NL63 (1×10 TCIDs/ml), Human coronavirus HKU1 (1×10 TCIDs/ml), MERS COV Florida (1.17×10 TCIDso/ml), Influenza A H1N1 (3.16×10 TCIDs/ml), Influenza A H3N2 (1×10 TCIDs/ml), Influenza B (3.16×10 TCIDs/ml), Human Rhinovirus 2 (2.81×104 TCIDs/ml), Human Rhinovirus 14 (1.58×10 TCIDs/ml), Human Rhinovirus 16 (8.89×10 TCIDs/ml), Measles (1.58×10 TCIDs/ml), Mumps (1.58×10 TCID/ml). Parainfluenza virus 2 (1.58×10 TCIDs/ml), Parainfluenza virus 3 (1.58×10 TCIDs/ml), Respiratory syncytial virus (8.89×10 TCIDs/ml), Enterovirus Type 68 (2007 Isolate) (1.51×10 TCIDso/ml), Haemophilus influenzae type b (1.35×10 CFU/ml), Nasal Wash (0.90%) 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 inoculate.

VARIANTS

The SARS-CoV-2 variant Alpha (UK B.1.1.7) (Detected out concentration 102 viral RNA copies/µL), Delta (Indian B.1.617.2) (Detected out concentration 0.9ng/mL), Gamma (B.1.1.28) (Detected out concentration 1.15 ng/mL), VUI-21ARP-03 (Indian B.1.617.3) (Detected out concentration 1.05 ng/mL) and Beta (South Africa B.1.351) (Detected out concentration 10 viral RNA copies/µL) by the SARS-CoV-2 Antigen Rapid Test at specific concentrations

LIMITATION OF DETECTION

The SARS-CoV-2 Antigen Rapid Test can detect out SARS-CoV-2 heat-inactivated virus strain as low as 1X102 TCID50/ml.

Precision

Intra-Assay & Inter-Assay

Within-run and Between-run precision has been determined by using five specimens of COVID-19 standard control. Three different lots of COVID-19 Antigen Rapid Test (Swab) have been tested using negative, -50% LOD, LOD, 2X LOD and 6X LOD standard samples. Ten replicates of each level were tested each day for 5 consecutive days. The specimens were correctly identified >99% of the time.

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. The following organisms were tested at no less than 1.0×108 orgml and all found to be negative when tested with the COVID-19 Antigen Rapid Test (Swab): Arcanobacterium, Pseudomonas aeruginosa, Candida albicans Staphylococcus aureus subspaureus, Corynebacterium, Staphylococcus epidermidis, Escherichia coli, Streptococcus pneumoniae, Moraxella catarrhalis, Streptococcus pygenes, Neisseria lactamica, Streptococcus salivarius, Neisseria subflava, Streptococcus sp group F, Chlamydia pneumoniae Legionella pneumophila Philadelphia Bordetella Pertussis A639, Mycoplasma Pneumoniae M129

Cross-reactivity Continued

Our Test Results indicated there is the cross reactivity between SARS-CoV-1 and SARS- CoV-2 at the concentration equal to or more than 1ng/ml in detection of SARS CoV-1 recombinant nucleocapsid protein. This is because SARS-CoV has high homology to the SARS-CoV-2.

Interfering Substances

The interfering substances below were spiked with negative, SARS-CoV-2 Antigen weak positive. No substances showed any interference with the COVID-19 Antigen Rapid Test (Swab). Substance (Concentration), Whole Blood (20l/ml), Mucin (50ug/ml), Budesonide Nasal Spray (200µl/ml), Dexamethasone (0.8mg/ml), Flunisolide (6.8ng/ml), Mupirocin (12mg/ml). Oxymetazoline (0.6mg/ml), Phenylephrine (12mg/ml), Rebetol (4.5µg/ml). Relenza (282ng/ml), Tamiflu (1.1ug/ml), Tobramycin (2.43mg/ml), HAMA (1mg/ml) and Biotin (0.1mg/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 self-collected 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 when symptoms including sudden onset of at least one of the following: cough, fever, shortness of breath, fatigue, decreased appetite, myalgia.
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 sam ling 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.
   If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility using the rules of your local authority. 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, migration/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 result 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.
7. Information of how to contact locally available support services. For advice on how to seek medical help or get tested for coronavirus (COVID-19) you can contact your state or territory health authority, Please see your local contact numbers below

STATE AND TERRITORY CONTACT NUMBERS

Australian Capital Territory Coronavirus Helpline (8am-8pm daily)
02 6207 7244
New South Wales Coronavirus Helpline (Service NSW 24/7)
137 788 1800 020 080
Northern Territory Coronavirus National Hotline (National Helpline) Queensland Coronavirus Helpline (134COVID)
134 268 1800 253 787
South Australia Coronavirus Helpline (9am-5 pm Daily)
1800 671 738 1800 675 398
Tasmanian Public Health Hotline (Coronavirus) Victoria Coronavirus Hotline (24/7) Western Australia Coronavirus Hotline 13COVID (8am-6pm Mon-Fri) 1800 595 **206**

Contact the TGA to report poor performance or usability issues in the self-test environment (report an issue via the Users Medical Device Incident Report, email: iris@tga.gov.au or call 1800 809 361)

BIBLIOGRAPHY

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

Number: 146573800 Effective Date: 2021-10-08

INDEX OF SYMBOLS

- For in vitro diagnostic use only

- Tests per kit

- Do not reuse

- Use by

- Consult Instructions for use

- Manufacturer
- Catalogue #

- 30°C Store between 2-30°C

- Do not use if package is damaged

- Lot Number

LOT

Sponsored By: AM Diagnostics Pty Ltd Unit 8, 25 Wicks Street Bayswater, WESTERN AUSTRALIA 6053 PH: 1800 472 743 **www.mycovidtest.com.au**

Hangzhou AllTest Biotech Co.,Ltd. #550, Yinhai Street Hangzhou Economic & Technological Development Are Hangzhou, 310018 PR. China Web www.alltests.com.cn Email info@altests com.c

BEFORE STARTING

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.
Make sure they are dry before starting.

PREPARE FOR THE TEST

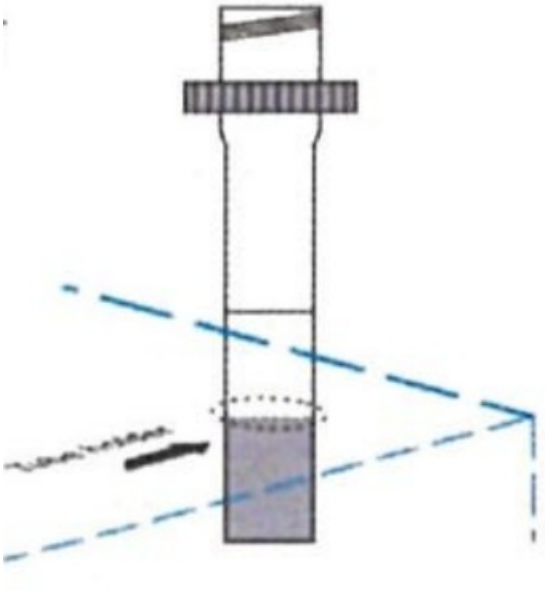
1A. Check the expiration date on the box. Do not use if the kit if it has been damaged or has expired
1B. Ensure kit is at room temperature for at least 30 minutes prior to use.

Open the box carefully as it will be used in a later step (1D). Do not open individual components until instructed.

Note: A timing device (clock, timer, phone etc.) is required, but not provided.

1C. Remove the cover of the tube with Extraction buffer.

1D. Put the Tube into the kit box tray holder before proceeding to the next step.



Note: Being careful not to spill the Tube contents.

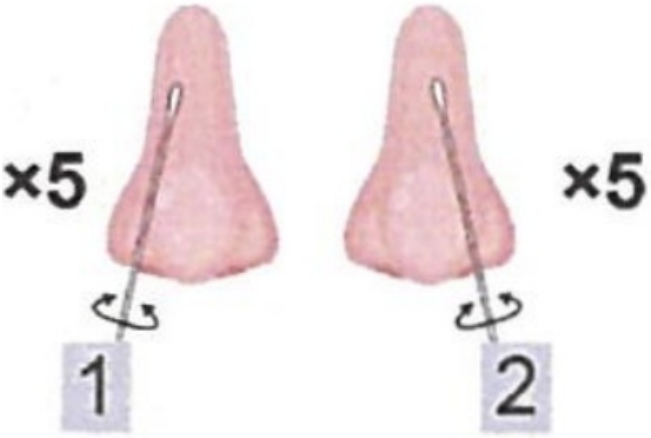
COLLECT THE NASAL SAMPLE

Keep fingers away from the Swab end.
A. Open Swab protective pouch Remove the sterile swab from the pouch

Touch the stick end only.

2B. Swabbing both nostrils.

Insert the soft end of the Swab into your nostril until you feel resistance (Approx. 2cm up your nose).



Slowly twist the swab, rubbing it along the insides of your nostril, 5-10 times against the nasal wall

Gently remove Swab from nostril.

Note:

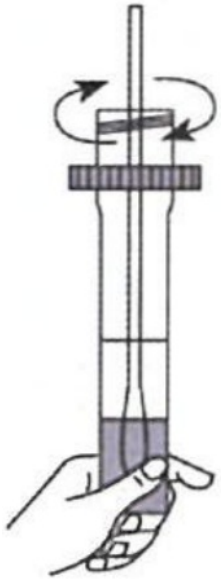
- This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
- When the nasal mucosa is damaged or bleeding, nasal swab collection is not recommended.
- If you are swabbing others, please wear a face mask. With children. you may not need to insert the swab as far into the nostril.

- For very young children, you may need another person to steady the child's head while swabbing.

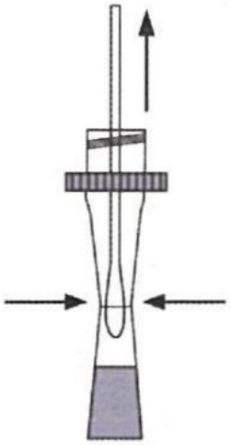
2C. Using the same Swab, repeat step 2B, in your other nostril. Withdraw the swab.

2D. Insert the Swab into the extraction Tube. Ensure it is touching the bottom and stir the swab to mix well.

Press the swab head against the tube and rotate the swab for **10-15 seconds.**



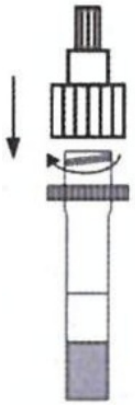
2E. Hold the Tube firmly with one hand. Remove the swab while squeezing the swab head against the inside of the Extraction tube.



Place the swab in the biosafety bag.

2F. Close the cap of the extraction tube.

Return the Tube to the Kit Box Tray holder before proceeding to the next step.

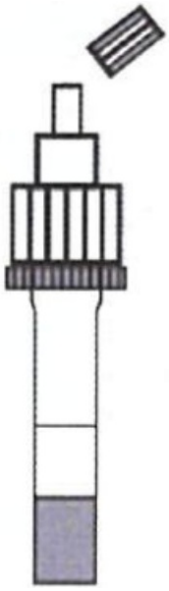


PERFORM THE TEST

3A. Remove the test cassette from the sealed foil pouch and use it within one (1) hour.

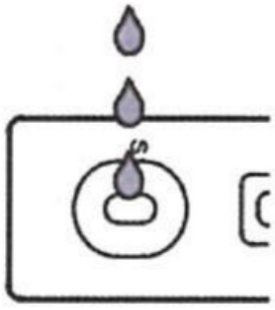
Note: Best results will be obtained if the test is performed immediately after opening the foil pouch. Place the test cassette on a flat and level surface.

3B. Open the small cap of the specimen extraction tube.



Do not move the test cassette during test developing.

3C. Invert the specimen extraction tube and add 3 drops of extracted specimen to the sample well (S) of the test cassette. Start the timer.



Secure white cap back on extraction tube and wait 15 minutes. 15 Min

Do not touch the Test Device during this period.

3D. Keep Test Device flat on table.

Read the result at 15 minutes.

Do not read the result earlier than 15 minutes or after 20 minutes

READ TEST RESULT

Please share our test result with your healthcare provider and carefully 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 COVID-19 test centre.

POSITIVE: *Two distinct coloured lines appear.

One coloured line should be in the control region (C) and another coloured line should be in the Test region (T)

***Note:** The intensity of the colour 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 colour in the test region (T) should be consider positive A positive result 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 o your local authorities. Your test result will be checked by a PCR confirmation test and you will be explained the next steps.

For All Positive results a Confirmatory PCR test by a laboratory is required. Please contact your local Covid Help Line on the reverse side of these instructions.

NEGATIVE RESULT: One coloured line appears in the contro

No apparent coloured line appears in the test line region (T) You are unlikely to have COVID-19. However, it is possible for this test t give a negative result that is incorrect la false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative.
If you experience symptoms such as headaches, migraines, fever, loss o sense of smell or taste, contact the nearest medical facility according to the rules of your local authority. In addition, you can repeat the test wit 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 yourself and hygiene rules must be observed, migration/traveling, attending events, etc., you should follow our local COVID guidelines/requirements.

DISPOSE THE TEST KIT

SA. After the test is completed, place all the components into the plastic Bio-safety bag (supplied)

58. Dispose according to local regulation

Before testing, scan the QR code to watch the how to use video, or visit **www.mycovidtest.com**.au/how-it-works/
For additional language instructions please visit **www.mycovidtest.com**.au/product-resources

Documents / Resources

	**ALL TEST INCP-502H Home Use Rapid Test** [pdf] User Guide INCP-502H Home Use Rapid Test, INCP-502H, Home Use Rapid Test, Use Rapid Test, Rapid Test, Test