



EN

English-Australia

REF

ARS-COV-2-A3001V1



Wonderful Capital
Biotechnology Group

PTV-110

AUS REP



COVID-19 Antigen SELF-Test

For use with nasal swab specimens



Please scan the QR code or use the URL below to access a digital version of the instructions, an on-line instructional video and information about accessing support services, including COVID-19 testing locations, from local state and territory health departments. Information on how to contact the TGA to report performance or usability issues.

www.wonderfulbiotech.com.au

INSTRUCTION FOR USE

Read the instructions for use completely before performing the test. For in vitro diagnostic and for self-testing use.

Product

WonderMed COVID-19 Antigen SELF-Test

Purpose

WonderMed COVID-19 Antigen SELF-Test for self-application is used for the detection of SARS-CoV-2 antigens in samples from the human anterior nasal cavity area. It is used to detect SARS-CoV-2 nucleoprotein antigens within 7 days of the onset of symptoms suspected of coronavirus infection. Positive test results can be used for early isolation and rapid treatment of suspected cases, but they cannot serve as a basis for a definitive diagnosis of coronavirus infection.

WonderMed COVID-19 Antigen SELF-Test can detect the SARS-CoV-2 Variants of Alpha, Beta, Gamma and Delta, but the type of the variant can not be distinguished.

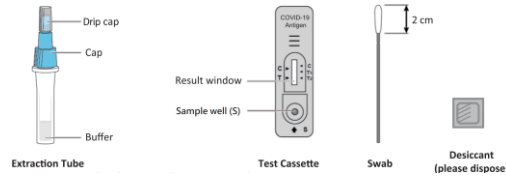
Important for self-application:

In case of a positive test result, please isolate yourself and contact your doctor or call the Corona hotline (SCAN THE QR CODE AT THE TOP). A positive test result must be confirmed by a PCR test.

Note that even if the result is negative, infection is not guaranteed to be excluded, as a low virus load or a possible sampling error can result in a wrong result.

Delivery & Contents

1. Test cassette & desiccant 2. Swab 3. Instruction for use 4. Extraction tubes with buffer, cap and drip cap



Note: The information about swab manufacturer, CE number and European representative are placed on swab package and outer packing box. The diagram is for reference only. See the real object for details. The appearance of extraction tube and color of its cap may be different from the actual product, which has no effect on normal use. An error of 0.3cm in the length of the sampling swab head will not affect results, it can be used normally.

MATERIALS REQUIRED BUT NOT PROVIDED

Watch/Timer Garbage bag

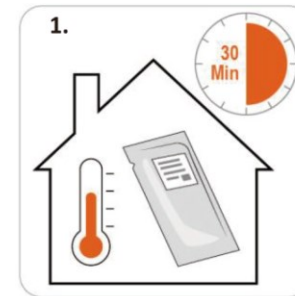
KIT SIZE	CONTENTS
2 Test	2 Test cassette, 2 Extraction tubes, 2 Nasal swab, 2 Instruction for use

Limitations and warnings

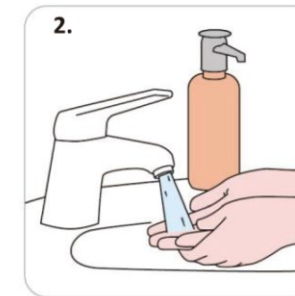
- The test kits should be stored at temperatures of 4-30°C and should not be exposed to direct sunlight or moisture. Before use, tests stored at low temperature should be brought to room temperature.
- Do not use expired and damaged products. The expiry date is printed on the outer packaging.
- Suitable for people aged 16 and over using independently. Children under 16 need use under supervision. Keep the test kits away from young children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
- The test cassette should be used as soon as possible after removal from the foil bag to avoid prolonged exposure to moisture, as these could affect the test result.
- Under room temperature (15-30°C) and humidity of less than 60%, the test kits must be used within half an hour after opening the packaging. If the humidity exceeds 60%, use immediately after opening the packaging.
- Do not freeze the test kits.
- The test set should be disposed after use in a lockable garbage bag in the household waste.
- Incorrect operation may affect the accuracy of the results, such as e. g. too little effective time in the buffer solution, too little or too much buffer in the solution, insufficient sample addition, inaccurate detection time, etc.
- False-negative results can occur when the swab is placed in a bag between sampling and evaluation.
- Do not suck the sample with your mouth.
- During the test, do not smoke, eat, drink alcohol, apply make-up or put in contact lenses, or take them out.
- Disinfect spilled samples or reagents with disinfectant.
- If the extraction reagent come into contact with the skin or eyes, wash / rinse the affected area with plenty of water. If irritation is found, contact your doctor.
- After the test, stow all components in a sealable plastic bag and dispose of them in household or residual waste.
- Wash hands thoroughly after test completion.

Test flow

I. PREPARATION



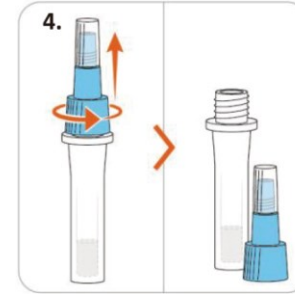
Bring all components of the test kit to room temperature (15 to max. 30 °C) 30 minutes before starting the test.



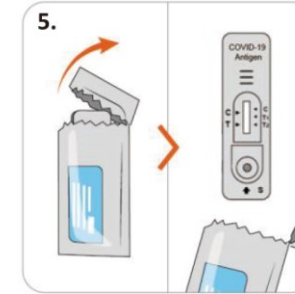
Wash your hands thoroughly.



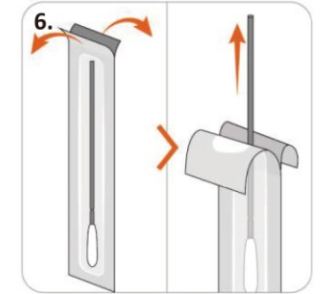
Have a clock ready or use a timer.



Unscrew the blue cap from the extraction tube. Don't spill the liquid.

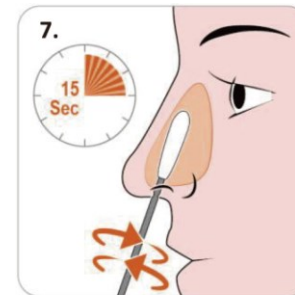


Unpack the test cassette and use this right away according to the following instructions.

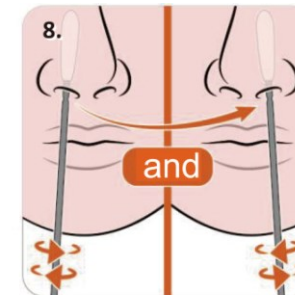


Unpack the swab.

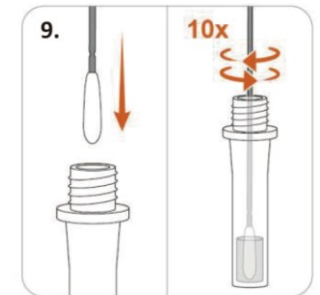
II. SAMPLING



Insert the swab approx. 2-2.5 cm deep into one nostril. The absorbent, the tip should be completely immersed in the nasal cover.

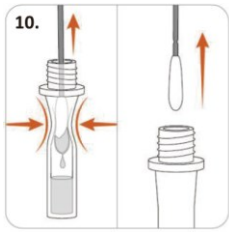


Wipe the swab along the inner wall of the nose in circular movements for about 15 seconds.

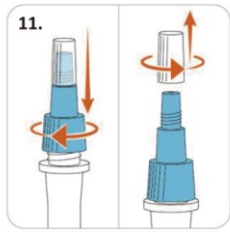


Repeat with the same swab in the other nostril.

Immerse swabs in extraction tubes with buffer solution and rotate 10 times. Let it work for 1 minute.



Then squeeze out the swab using the extraction tube. Collect the liquid in the tube. Remove the swab and put it in the garbage bag.



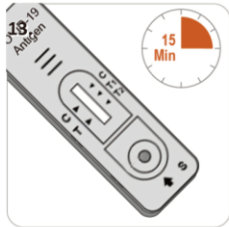
Close the extraction tube with the cap and unscrew the drip cap. Do not shake!



Turn the tube upside down and add 2 to a maximum of 3 drops to the sample well (s) of the test cassette. Do not move the test cassette.

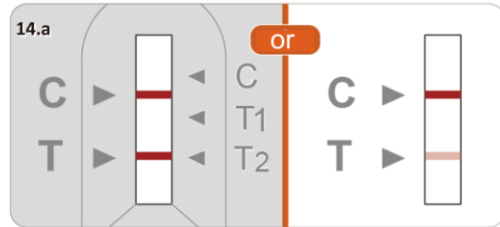
III. RESULTS INTERPRETATION

Look closely! The presence of any Test (T) line, no matter how faint is a positive result.



Read the result in the result window after 15 minutes.

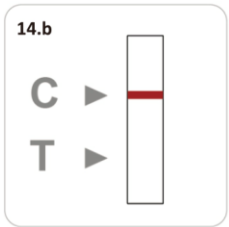
C = Control line
T = Testing line



POSITIVE

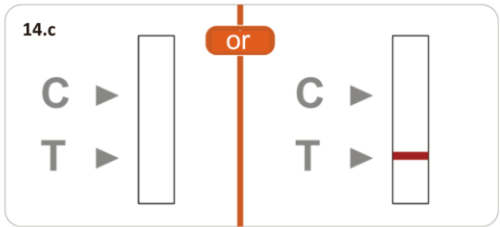
POSITIVE

You could be contagious. Isolate yourself and contact your family doctor or call the Corona hotline.



NEGATIVE

They are not highly contagious. Nevertheless, hygiene measures follow.



INVALID

INVALID

Repeat the test with a new test.

IV. DISPOSAL



After the test, stow all components in a sealable plastic bag and dispose of them in household or residual waste.



Wash your hands thoroughly.

Restrictions of the test procedure

- The results of this product should not be considered a definitive diagnosis and are for clinical reference only. The judgment should be based on the RT-PCR results, clinical symptoms, prevalence of infectious diseases, and other clinical data.
- If the virus antigen content in the sample is below the detection limit, the test result may be negative, particularly if testing is not performed within the first 7 days of symptom onset.
- As the disease lasts, the number of antigens in the sample may decrease and the results may be negative 7 days after symptoms appeared compared to the RT-PCR test.
- Due to the limitations of testing procedures, negative results cannot rule out the possibility of infection and cannot rule out the possibility of infection with another type of respiratory virus.
- Due to the limitations of testing procedures, positive result should not be viewed as a definitive diagnosis, but should be assessed in the context of clinical symptoms and other diagnostic methods. A positive result cannot necessarily determine whether a person is infectious.
- If ongoing suspicion of infection, high risk setting or other epidemiological reasons, but test result was negative, test twice within two or three days with at least 24 hours and no more than 48 hours between tests is recommended.
- Please contact the TGA for locally support services or reporting poor performance and 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).

Quality

The test cassette has a test line (T) and a control line (C) on the surface of the membrane. Neither the test nor control line is visible in the results window before a sample is applied. The control line is used for procedural control and should be displayed whenever the test procedure is properly carried out and the control line reagents work. The occurrence of the control line (C) confirms sufficient sample volume, sufficient membrane discharge and correct process technology.

Test principle

The rapid test is based on the GICA principle, whereby the nitrocellulose membrane is coated with monoclonal coronavirus (SARS-CoV-2) antibody 2 and goat-anti-mouse IgG antibody, the monoclonal coronavirus (SARS-CoV-2) antibody 1 fixed on a gold conjugate pad solid phase. When the antigen is contained in the sample, it combines with the appropriate gold-labelled monoclonal antibodies to form a complex and moving forward under the chromatography on the membrane, then combines with the coated antibody on the test line to form Au-novel coronavirus (SARS-CoV-2) monoclonal antibody 1-antigen-novel coronavirus (SARS-CoV-2) monoclonal antibody 2 complex to condense into a red band (Test line, T). Excess particles are intercepted at the control line (C). If a red line appears in the test line area (T), this should be considered a positive result. If no antigen is included in the sample, no complex can form on the test line, and no red line appears, which is a negative result. The gold-labelled monoclonal antibody binds to the coated goat-anti-mouse IgG antibody on the control line to form a complex of "Au-coronavirus (SARS-CoV-2) monoclonal antibody 1-goat-anti-mouse-IgG antibody", regardless of whether the sample contains antigen, and the color is developed as a cohesion (Control line, C). If the control line is not visible, the test must be repeated with a new cassette.

What your results mean and what to do with your results

Positive result A positive result means it is very likely you have SARS-CoV-2 infection. Please isolate yourself, stay at home, avoid contact with your roommates as much as possible and don't receive visitors. Contact your doctor or call the Corona hotline. A positive test result must be confirmed by a LABORATORY PCR test.

Negative result This means you probably don't have SARS-CoV-2 infection. Pay attention! A negative result of a self-test is not 100% reliable. So stay careful. You still need to take precautions. Keep your distance, wear a mouth mask and wash your hands often.

Invalid result An invalid result means this test was unable to determine whether you have SARS-CoV-2 or not. A new test is needed to get a valid result.

Variants can be detected

The list of variants of COVID-19 the test can detect (eg. alpha, beta, delta, etc.)

Possible Risk

Slight discomfort during the nasal sample collection.

Possible false test results may occur, if symptoms continue, you should repeat the test after 1-2 days, as the coronavirus may not be detectable in the very early phases of infection. You are also advised to continue following local guidelines for self-isolation and consult your doctor.

Explanation of the symbols

	Consult instructions for use		Keep dry
	Temperature limit	LOT	Batch code
	Do not re-use	IVD	In vitro diagnostics medical device
	Manufacturer		Date of Manufacture
	Use-by date		contains sufficient for <n> tests
	Keep away from sunlight	/	/

Manufacturer information

MANUFACTURER / POST-SALE SERVICE UNIT

Qingdao Hightop Biotech Co., Ltd.

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