SecurePlus®

REF : ICO - A502

English

# COVID-19 (SARS-CoV-2) Antigen Test Kit Instruction for Use

## INTENDED USE

COVID-19 (SARS-CoV-2) Antigen Test Kit is a testing device that uses an immunochromatographic assay technique to qualitatively detect the presence of the nucleocapsid(N) protein antigen of the SARS-CoV-2 virus (the virus that causes COVID-19 disease) in human nasal swab specimens collected from symptomatic persons within 7 days of symptom onset.

The test is used as an aid in the diagnosis of SARS-CoV-2 viral infections. The test is intended to be used in the home or similar environment by a lay person.

## PRINCIPLE

COVID-19 (SARS-CoV-2) Antigen Test Kit is a immunoassay for the qualitative detection of the SARS-CoV-2 antigen in human nasal swab specimens. The test device has a conjugation pad with a colouring material and a membrane which has a Test Line (T) coated with a Detection Antibody. If the sample contains SARS-CoV-2 antigen, a coloured line appears in the test line region, indicating a positive result. If the sample does not contain SARS-CoV-2 antigen, no coloured line appears in this area, indicating a negative result. As a procedural control, a coloured line always appears in the control line region, indicating that the correct sample volume has been added and the membrane has been wetted through.

## STORAGE AND STABILITY

1. Store the test kit in the original packaging at 2°C- 30°C. Do not freeze. Test kit contents remain stable until the expiration date printed on the outer packaging.
2. After opening the pouch, the test should be used within one hour.
3. Prolonged contact with hot and humid environment will cause the product to deteriorate.

## LIMITATION

1. The test is for the qualitative detection of SARS-CoV-2 antigen in human nasal swab specimens. It does not indicate the quantification of the virus.
2. The test is for in vitro diagnostic use only and for self-test use only.
3. A negative test result does not completely rule out SARS-CoV-2 infection, particularly if you have been in contact with the virus and/or if you have symptoms.
4. A negative test result does not mean that a person is not infectious and does not rule out infection with another type of respiratory virus.
5. A positive result cannot necessarily determine whether a person is infectious.
6. The test should be performed within the first 7 days of symptom onset when viral shedding /viral load is highest.
7. If the test is performed more than 7 days after symptom onset, false negative results may occur.
8. The test is less reliable in the later phase of infection and in asymptomatic persons.

## PERFORMANCE CHARACTERISTICS

1. Clinical performance

COVID-19 (SARS-CoV-2) Antigen Test Kit and a PCR-based test was conducted by lab professionals involving 430 participants. Compared with the gold standard of detection methods - nucleic acid detection, the sensitivity is 70% 8-10 days of symptom onset.

Using COVID-19(SARS-CoV-2) Antigen Test Kit by professional was compared to the RT-PCR kit. The 130 positive confirmed cases showed 3 false negatives and the 300 negative confirmed cases showed 5 false positives. Therefore, the test is intended as an aid in diagnosis of symptomatic individual meeting the case definition for COVID-19 within the first 7 days of symptom onset.

| Professional clinical result according to the date of onset | | | |
|---|---|---|---|
| Days after symptom onset (d) | Antigen Test | RT-PCR | Sensitivity |
| 0-3 | 56 | 56 | 100.00% |
| 4-7 | 71 | 74 | 95.95% |
| >7* | 7 | 10 | 70% |

*: Patients will be excluded when symptoms have been present for ⩾ 7 days as it will affect accurately reflect the clinical performance of the device.

| Professional clinical result according to the Ct value by RT-PCR | | | |
|---|---|---|---|
| Ct value | Antigen Test | RT-PCR | Sensitivity |
| Ct⩽25 | 30 | 30 | 100.00% |
| 25<Ct⩽30 | 76 | 76 | 100.00% |
| Ct>30 | 21 | 24 | 87.50% |

**Clinial result summary**

| Method | | RT-PCR | | Total Results |
|---|---|---|---|---|
| Antigen Test | Results | Positive | Negative | |
| | Positive | 127 | 5 | 132 |
| | Negative | 3 | 295 | 298 |
| Total Results | | 130 | 300 | 430 |
| Clinical sensitivity | | 97.69 % (95%CI* 93.43% to 99.21%) | | |
| Clinical specificity | | 98.33% (95%CI* 96.16% to 99.29%) | | |
| Accuracy | | 98.14% (95%CI* 96.37% to 99.05%) | | |

Usability Study: A Clinical Performance Study involve 90 laypersons who carried out a self-test using the test. The results were that the Overall Percent Agreement (Accuracy) was 97.8% and the sensitivity and specificity were 96.67% and 98.33%, respectively. The overall feedback from a Usability Study involving 100 laypersons was that the test was user-friendly and easy to use.

| Self-test Clinical Result | | | | |
|---|---|---|---|---|
| | Antigen | PCR | Sensitivity | Specificity |
| Positive | 29 | 30 | 96.67% | / |
| Negative | 59 | 60 | / | 98.33% |
| 95% confidence interval | | | 83.33%~99.41% | 91.14%~99.71% |

2.Analysis performance

(1).Limit of Detection(LoD): The limit of detection of the test was confirmed to be$1.0x10^2$ $TCID_{50}$/mL.

(2).Cross-reactivity study: The following 27 microorganisms had no imnact on the performance of the COVID-19 (SARS-CoV-2) Antigen Test Kit:

| Virus or organisms | | |
|---|---|---|
| Respiratory syncytial virus Type A | MERS-CoV | Enterovirus EV70 |
| Respiratory syncytial virus Type B | SARS-CoV | Candida albicans |
| Seasonal influenza A H1N1 virus | ADV 1 | Parainfluenza virus 4 |
| Influenza A H3N2 virus | ADV 2 | Legionella pneumophila |
| Influenza A H5N1 virus | ADV 3 | Mycobacterium tuberculosis |
| Influenza B Yamagata | ADV 4 | Streptococcus pyogenes |
| Influenza B Victoria | ADV 5 | Bordetella pertussis |
| Rhinovirus A2 | ADV 7 | Pneumocystis jirovecii |
| Rhinovirus B52 | ADV 55 | Parainfluenza virus 1 |
| Human coronavirus 229E | Human coronavirus HKU1 | Parainfluenza virus 2 |
| Human coronavirus Oc43 | Streptococcus pneumoniae | Parainfluenza virus 3 |
| Staphylococcus aureus | Mycoplasma pneumoniae | Haemophilus influenzae |
| Human coronavirus NL63 | Chlamydia pneumoniae | Coxsackie virus CA16e |
| Human Metapneumovirus A2 | Coxsackie virus A24 | Coxsackie virus B5 |

(3).Inference study: An interference study showed that the following potential interfering substances did not affected the performance of COVID-19 (SARS-CoV-2) Antigen Test Kit:

| Interfering substances | |
|---|---|
| Human blood (EDTA anticoagulated) | Zanamivir |
| Histamine hydrochloride | Ribavirin |
| Phenylephrine Hydrochloride | Mucin |
| Oxymetazoline hydrochloride spray | Peramivir |
| physiological seawater nasal spray | Lopinavir |
| Beclomethasone dipropionate nasal aerosol | Ritonavir |
| Triamcinolone acetonide nasal spray | Arbidol |
| Budesonide nasal spray | Levofloxacin |
| Mometasone furoate nasal spray | Azithromycin |
| Fluticasone propionate nasal spray | Ceftriaxone |
| HAMA（Human anti-mouse antibody mixture） | Meropenem |
| Oseltamivir phosphate | Tobramycin |
| Alpha interferon | Hexadecadrol |
| Biotin | Flunisolide |

## WARNING AND PRECAUTIONS

1. Before using test, carefully read instructions for use.
2. Keep test kit and kit components out of the reach of children and pets before and after use.
3. Do not use the test if you are prone to nose bleeds.
4. If samples are not taken in accordance with the instructions, it can have a significant impact on the test results.
5. Do not wear coloured lens (glasses or contact lens) when interpreting the test result, as coloured lens can affect the interpretation of the test result.
6. Do not use if the Test kit package is damaged.
7. Do not reuse any kit components or mix components from different kit lots or different products.
8. Keep test kit components sealed prior to use.
9. When handling this test kit, do not let your hands or other foreign objects directly touch the result window of the device or the membrane of the strip.
10. If the assay buffer liquid gets into your mouth, eyes or comes into contact with your skin, immediately gargle water in your mouth several times (if it got into your mouth) or rinse the affected area with plenty of running water (if it got into your eyes or came into contact with your skin).If unwell, seek medical assistance.
11. Repeat testing within 1 to 3 days is recommended if ongoing suspicion of infection, high risk setting or occupational or other requirement.
12. Use test on persons aged 2 years or older. Do not use test on persons under 2 years old. An adult should carry out the test on persons aged 2 to 15 years.
13. Do not smoke, eat or drink while carrying out the test.
14. If you have problems with your hands or vision, an adult without those problems should assist you with the swabbing and testing process.

## VARIANTS DETECTABLE BY THIS TEST

The test has been tested and proven to detect multiple Variants of COVID-19, including Alpha, Beta, Gamma, Delta, and the Omicron Variant. It should be noted that the manufacturer' s R&D team is constantly working to ensure that these tests can detect any new variants that become known.

## MEDICAL DEVICE INCIDENT REPORT

If there are poor performance or usability issues, please contact the TGA to report an issue via the Users Medical Device Incident Report, email iris@health.gov.au. or call 1800 809 361.

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Tel: +61-2-9881 0368

# COVID-19 (SARS-CoV-2) Antigen Test Kit

Note: Use test only one time.

SecurePlus®

Scan the QR code or visit our website for instructional video, product information and IFU:

https://www.plusmedical.com.au/cov-manuals2

**For support and user assistance, Contact us on:**

**1300 885 823**

**The service is available between 9 am and 7 pm (AEST)or 9am and 8pm (AEDT),7 days a week.**

| Components | 1 Test/Kit | 5 Tests/Kit | 20 Tests/Kit |
|---|---|---|---|
| 1. Test Cassette | 1 x | 5 x | 20 x |
| 2. Extraction Buffer Tube | 1 x | 5 x | 20 x |
| 3. Disposable Swab | 1 x | 5 x | 20 x |
| 4. Biohazard Specimen Bag | 1 x | 5 x | 20 x |
| 5. Instruction for Use | 1 x | 1 x | 4 x |

Materials required but not provided : Timer

**For the sterilized swab**

CE 0197 MDR 2017/745EU Hangzhou Yiguoren Biotechnology Co., Ltd.

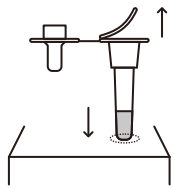
CE 0197 MDD 93/42/EEC Jiangsu HanHeng Medical Technology Co., Ltd.

| SYMBOLS | | | |
|---|---|---|---|
| 2 | Do not re-use | | Use-by date |
| IVD | In vitro diagnostic medical device | | Keep away from sunlight |
| 2°C–30°C | Store between 2-30°C | | Keep dry |
| | Consult instructions for use | | Do not use if package is damaged and consult instructions for use |
| LOT | Batch code | | Manufacturer |
| Σ | Contains sufficient for <n> tests | REF | Catalogue number |

**1**

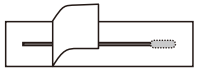
Wash your hands.

**2**



Tear the aluminum foil on the extraction buffer tube. Place extraction tube into box tube stand.

**3**



Open the swab package and take out the swab.
**Note : Do not touch the swab tip with finger.**

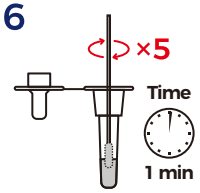
**4**


Tilt your head back slightly. Insert the swab about 1.5 to 2.5 cm into one nostril. Gently rotate the swab at least five times against the nasal wall.

**5**

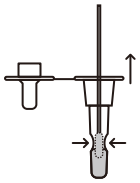

Insert the same swab about 1.5 to 2.5 cm into the second nostril. Again, gently rotate the swab at least five times against the nasal wall.

**6**



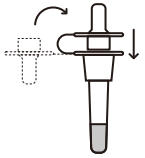

Place the swab in the extraction tubea and rotate the swab against the walls of the tube 5 times. Allow the swab to stand in the extraction buffer tube for 1 minute.

**7**



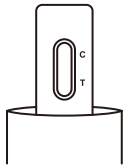
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.

**8**



Press the nozzle cap tightly onto the tube.

**9**

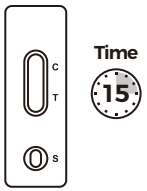



Open the foil pouch and take out the test device.

**10**


3 drops must be added to the specimen well.

**11**



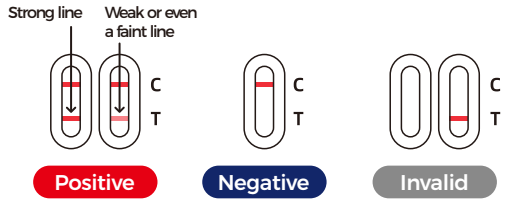

Read the result at 15 minutes. Do not interpret the result after 20 minutes.

**12**

Place the used test components into a biohazard specimen bag which can be sealed and dispose of in general waste.

**13**

Wash your hands.




**Note: A weak C line could be observed in some cases where strong SARS-CoV-2 positive results are obtained.**

## Interpretation of results

**POSITIVE: Two colored lines appear on the membrane. One line appears in the control region (C) and the other line appears in the test region (T).**

**NEGATIVE: Only one colored line appears in the control region (C). No colored line appears in the test region (T).**

**INVALID: Control line fails to appear.**

## Caution

**For positive COVID-19 results: If you test positive, follow current Department of Health and Aged Care advice (https://www.health.gov.au/topics/covid-19/testing-positive). For e.g.,**
**If you have a Covid-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.**
**If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the healthdirect helpline on 1800 022 222.**
**If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.**
**For invalid results: Please repeat testing using a freshly collected sample and new test cassette. Report repeated invalid results to the sponsor.**
**Test results of this kit are for clinical reference only. It is recommended that a comprehensive analysis of the disease be conducted based on clinical manifestations of patients and other laboratory tests.**
**Result interpretation: False positive results may occur from improper sample collection, not following this instruction guide.**