admin@bigstart.com.au
1800 052 007

INSTRUCTION VIDEO

V-CHEK

2019-nCoV Ag Rapid Test Kit (Immunochromatography forself-testing)

PLEASE READ ALL OF THE INFORMATION IN THE INSTRUCTIONS FOR USE CAREFULLY BEFORE USING THE TEST

Catalog Numbers:
0685C2X001 (1 Test/Kit) 0685C2X005 (5 Tests/Kit) 0685C2X025 (25 Tests/Kit)

INTENDED USE

This kit is used for the qualitative detection of N-protein antigen from SARS-CoV-2 virus in human NASAL SWAB specimens. This is used to aid in the diagnosis of COVID-19 infection. This kit can be used for individuals with symptoms or other reasons to suspect COVID-19 infection, within the first 7 days following the onset of symptoms.

- A positive result indicates COVID-19 infection. The RAT is a presumptive test only.
- Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- A negative result should be treated as presumptive. It does not rule out 2019-nCoV infection. Negative results should be considered in the context of a patient's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19. Confirm with a PCR test, if necessary.

For in vitro use only. Suitable for self-testing use.

PRINCIPLE

This test is a qualitative membrane-based immunoassay for the detection of SARS-CoV-2 antigens in human nasal (NS) swab specimens. When the antigen in the sample reaches the test area (T) of the membrane, it will form a coloured line. Absence of this coloured line suggests a negative result. To ensure the test is carried out properly, a coloured line will appear at the Control area (C), if the test has been performed correctly.

CONTENT OF THE TEST

REF Component	0685C2X001	0685C2X005	0685C2X025
Pouch (test cassette and desiccant)	1	5	25
Swab	1	5	25
Tube with buffer	1	5	25
Biohazard bag	1	5	25
Instructions for use	1	1	25
Tube Stand	NA	NA	1

Note:

1. Each individual sealed pouch contains one test cassette and one desiccant pouch (The desiccant pouch is for storage purposes only).
2. The components in different lots of the kit cannot be mixed.
3. The test strip includes: Gold conjugate (COV19-PS-Mab1-gold colloid, host animal of COV19-PS-Mab1: mouse), Test line (COV19-PS-Mab2, host animal: mouse) and Control line (Host animal: goat).

Materials required but not provided

1. Timer

STORAGE

1. Store at 2°C - 30°C.
2. Keep away from direct sunlight, moisture and heat.
3. Expiration date and lot No.: see label. Do not use after expiry.
4. Do not freeze any contents of the test.

PRECAUTIONS

1. Do not swallow.
2. Read the instructions for use carefully before starting the test.
3. The components in different lots of the kit cannot be mixed.
4. Do not use the kit contents beyond the expiration date printed on the outside of the box.
5. Do not reuse the test cassette, tube or swab.
6. Do not touch swab tip when handling the swab.
7. The user should never open the foil pouch of the test cassette until it is ready for immediate use.
8. Do not use the kit if the pouch is punctured or not well sealed. Do not use any damaged or dropped test cassette or material.
9. Testing should be performed in an area with adequate ventilation.
10. Inadequate or inappropriate sample collection, processing, storage and transport may yield a false positive result or a false negative result.
11. To obtain accurate results, do not use visually bloody or overly viscous samples.
12. To obtain accurate results, an opened and exposed test cassette should not be used.
13. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
14. Children under the age of 18 taking the test should be supervised by an adult.
15. Wear safety mask or other face covering when collecting swab specimen from a child or another person.
16. Use of Nitrile, Latex (or equivalent) gloves is recommended when handling samples (not included).
17. The main component of sample buffer is phosphate buffer. If the solution contacts the skin or eye, flush with plenty of water.
18. Wash hands thoroughly after handling.
19. Disposal of the used components: all specimens and the used kit has an infectious risk. Discard the used test according to local regulations with the included biohazard bag.

LIMITATIONS

1. Tests are for aiding in diagnosis only. Risk of false negative results if testing is not performed within the first 7 days of symptom onset.
2. Recommend repeat testing within 1-2 days if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
3. A positive/negative result cannot necessarily determine whether a person is infectious. Test performance depends on the amount of virus (antigen) in the sample. It may or may not correlate with viral culture results performed on the same sample.
4. The test kit must be at room temperature (15~30°C//59~86°F) before use, otherwise the results may be incorrect.
5. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
6. Reading time less than 15 minutes may lead a false negative result; Reading time more than 20 minutes may lead a false positive result.
7. Positive test results do not rule out co-infections with other pathogens.
8. Negative test results are not intended to rule in, or rule out, other viral or bacterial infections or another type of respiratory virus.
9. Negative results should be treated as presumptive
10. Users should test specimens as quickly as possible after specimen collection.
11. If the sample volume is not enough, the test cannot be carried out successfully.

TEST PROCEDURE CAUTIONS

Caution:

1. ***Please read the instructions for use carefully before starting the test.***
2. ***Familiarize yourself with the contents of the test kit in advance without opening the packaging of the components.***
3. ***The test cassette should be used within 1 hour of removal from the foil pouch.***
4. ***The test kit must be at room temperature (15 ~ 30°C//59~86°F) for 30 minutes before testing.***
5. ***Use of gloves is recommended when conducting testing.***
6. ***Do not remove the swab until ready for sample collection and do not touch the swab tip.***

INTERPRETATION OF TEST RESULTS

This test can only perform qualitative detection of 2019-nCoV antigen.
Positive Result: If both C and T lines are visible at 15 minutes, the test result is positive and valid. Even faint or weak T lines are considered a positive result.
Negative Result: If a coloured line is visible in the Control area(C), and no coloured line appears in the test area (T), the result is negative and valid.
Invalid Result: The test result is invalid if a coloured line does not form in the Control area(C). The sample must be re-tested, using a new test.

FREQUENTLY ASKED QUESTIONS

1. How accurate is the test?

The performance of Test was established with 808 clinical samples.

2019-nCoV Ag Rapid Test Kit (Immunochromatography)	Comparative RT-PCR Test Result		
	Positive (+)	Negative (-)	Total
Detected Positive	280	3	283
Detected Negative	10	515	525
Total	290	518	808
Sensitivity	96.55%, 95% CI (93.77, 98.12)		
Specificity	99.42%, 95% CI (98.31, 99.80)		
Accuracy	98.39%, 95% CI (97.27, 99.06)		

A usability study was performed with 130 lay people. The results showed that the instructions provided with the $TCID_{50}$/mL or less. 129/130 of users responded the instructions were easy to understand. 128/130 responded the procedure was easy to perform. 130/130 of users responded the test result was easy to read and interpret.129/130 responded the test was overall easy to use.

2. Can any substance interfere with the test?

No interference has been observed when testing the following substance: Whole Blood, Tamiflu (Oseltamivir), Ibuprofen, Naphthoxoline hydrochloride nasal drops, Tetracycline, Mucin Chloramphenicol, Fisherman's Friend, Erythromycin, Compound, Benzocain Gel, Tobramycin, Cromoglycate, Throat spray (Menthol), Sinex (Phenylephrine Hydrochloride), Mupirocin Afrin (Oxymetazoline), Throat lozenge (Menthol) or Fluticasone propionate spray.

No cross reactivity has been observed when testing the following specimen: HCoV-HKU1, Staphylococcus aureus, Streptococcus pyogenes, Measles virus, Paramyxovirus parotitis, Adenovirus 3, Mycoplasma pneumonia, Haemophilus influenza, Parainfluenza virus 1-4, Human Metapneumovirus, Human coronavirus OC43, Human coronavirus 229E, Human coronavirus NL63, MERS-Coronavirus EMC/2012, SARS-coronavirus, Bordetella parapertussia, Influenza B (Victoria strain), Influenza B (Y strain), Influenza A (H1N1 2009), Influenza A (H3N2), Avian influenza virus (H7N9), Avian influenza virus (H5N1), Epstein-Barr virus, Enterovirus CA16, Rhinovirus, Respiratory syncytial virus, Streptococcus pneumonia, Candida albicans, Chlamydia pneumonia, Bordetella pertussis, Pneumocystis jirovecii, Mycobacterium tuberculosis, Legionella pneumophila, Negative Nasal Matrix.

3. Can the test detect different variants of Covid-19?

Yes, the following inactivated cultures of COVID-19 mutant variants can be detected by the V-Chek test:
- **SARS-CoV-2 Isolate:** USA-WA1/2020 can be detected by the V-Chek test at concentrations of 100 $TCID_{50}$/mL or more.
- **Alpha** (B.1.1.7), **Delta** (B.1.617.2) and **Kappa** (B.1.617.1), **Omicron** (BA.1, BA.1.1, BA.2, BA.3) variants can be detected by the V-Chek test at concentrations of 200 $TCID_{50}$/mL or more.

4. How do I know that the test was run properly?

A coloured line will appear in the control area (C) of the test midstream if the test has been properly performed. If this line is not visible, then the test has been incorrectly performed & you must run a new test or call the Customer Support Helpline on 1800 052 007.

5. What should I do if the result shows positive?

- Note that you are currently suspected of COVID-19 infection
- Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance
- Individual states and territories will provide further information on how a positive RAT will be recorded

6. What should I do if the result shows negative?

- Continue to comply with all local applicable rules and protective measures
- Be aware that even if the test is negative, an infection may occur or be present
- In case of suspicion, repeat the test after 1-2 days and comply with local self-isolation guidelines.

7. What should I do if the result shows invalid?

- Possibly caused by incorrect operation
- Repeat a test, using a new test
- If test result is still invalid, contact the distributor, or the store where you bought the product, or call the Customer Support Helpline on **1800 052 007** with the lot number.

ASSISTANCE

Customer Support Helpline
Phone: 1800 052 007 – Hours are: 9am-7pm (AEST), 7 days
Email: admin@bigstart.com.au
Website: findmycovidtests.com.au

LOCAL HEALTH CONTACT

Australian Capital Territory Department of Health	☎ 02 6207 7244	health.act.gov.au/
New South Wales Department of Health	☎ 137 788	health.nsw.gov.au/
Northern Territory Department of Health	☎ 1800 020 080	health.nt.gov.au/
Queensland Department of Health	☎ 134 268	health.qld.gov.au/
South Australian Department of Health	☎ 1800 253 787	sahealth.sa.gov.au/
Tasmanian Department of Health	☎ 1800 671 738	health.tas.gov.au/
Victorian Department of Health	☎ 1800 675 398	dhhs.vic.gov.au/
Western Australian Department of Health	☎ 1800 595 206	healthywa.wa.gov.au/

TGA Contact Information for Reporting Poor Performance and Usability Issues: Call 1800 809 361 or email iris@health.gov.au

REFERENCES

1. Center of Disease Control and Prevention. Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19. May 22.
2. Wu F, Zhao S, Yu B, et al. A new coronavirus associated with human respiratory disease in China. Nature. 2020; 579:265-9.
3. https://www.who.int/publications/i/item/antigen-detection-in-the-diagnosis-of-sars-cov-2infection-using-rapid-immunoassays

KEY TO SYMBOLS USED

Consult instructions for use
Store at 2°C~30°C
Use-by date
Manufacturer
Batch code
Do not reuse
In vitro diagnostic medical device
Contains sufficient for n tests
Keep away from Sunlight
Date of Manufacturer
Catalogue number
Keep Dry
Do not use if package is damaged

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2019-nCoV Ag Rapid Test Kit

Immunochromatography forself-testing

findmycovidtests.com.au
For video + alternate languages

NOTE: Single use test only. Test within 7 days of symptom onset. Test should be performed by an adult or under adult supervision

TEST KIT

TEST CASSETTE

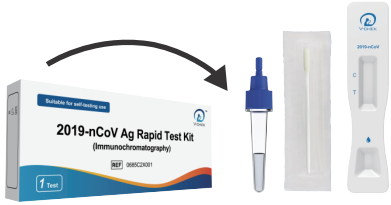
SWAB

TUBE WITH BUFFER

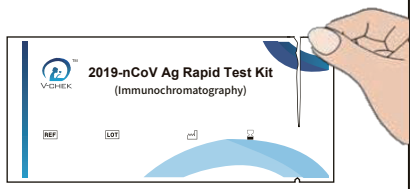
TEST PROCEDURE STEPS

1 Wash hands with soap

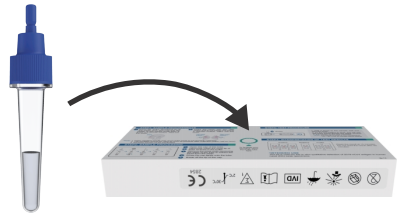
2 Remove test components



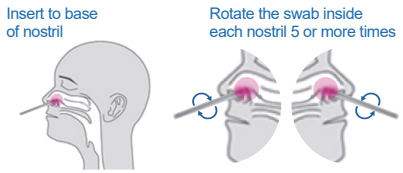
3 Test cassette found inside pouch



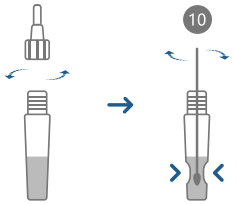
4 Place tube in cutout hole in the box



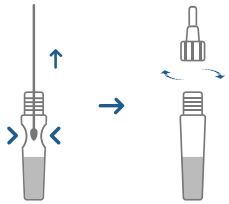
5 Swab nose



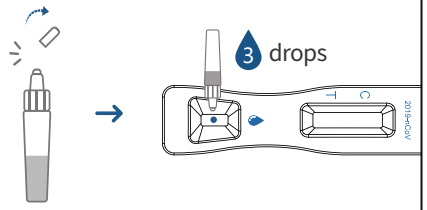
6 Put swab into buffer tube and rotate swab 10 times while applying pressure with your fingers



7 Remove swab and pinch excess fluid from swab tip with buffer tube

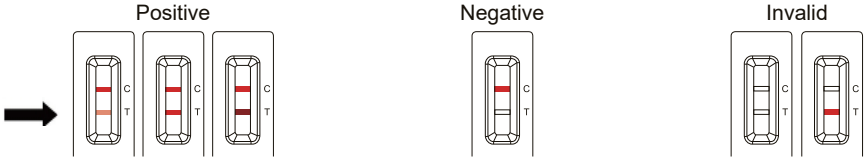


8 Screw cap onto tube, break tip,add 3 drops to test cassette



9 Check results at 15minutes, NOT after 20 minutes

Look Closely!
A weak or even faint line is still a positive result!



For positive tests;
Comply with local seif-isolation guidelines.
Individual states and territories will provide further information on how a positive RAT will be recorded.
Comply with local self-isolation guidelines.

Monitor for symptoms. In case of suspicion, repeat the test after 1-2 days.

Re-test or call
1800 052 007

10 Dispose using enclosed bag and wash hands

Please scan the QR code to watch the instructional video alternatively visit: findmycovidtests.com.au

1800 052 007 (9am-7pm AEST)