V-CHEK

INSTRUCTION VIDEO

COVID-19 Antigen Saliva Test

For self-testing

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

Catalogue Number:
0699C8X001 (1 Test/Kit) 0699C8X005 (5 Tests/Kit)
0699C8X003 (3 Tests/Kit) 0699C8X020 (20 Tests/Kit)

INTENDED USE

The COVID-19 Antigen Saliva Test is a lateral flow immunoassay intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2 in saliva specimens from individuals with symptoms or other symptoms that may suggest a COVID-19 infection. A positive result indicates the presence of viral antigens and additional testing is necessary. Positive results do not rule out bacterial infection or coinfection with other viruses. A negative result should be treated as presumptive and does not rule out COVID-19 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. If necessary, confirm with a molecular assay. The Test Card is intended for use in the first 7 days of symptom onset.
The COVID-19 Antigen Saliva Test is intended for use by laypersons and enables self-testing at home or other locations.
This is a screening test only. To confirm results take a laboratory PCR test.

PRINCIPLE

The COVID-19 Antigen Saliva Test is a qualitative membrane-based immunoassay for the detection of SARSCoV-2 antigens in human saliva samples.
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.

CONTENTS OF THE TEST KIT

'Lollipop' Saliva Swab, Test Cassette, Instructions For Use & Biosafe Disposal Bag.

WHAT ELSE DO YOU NEED?
1. Timer

STORAGE

1. Store the packaged test between 2-30°C.
2. Keep away from direct sunlight, moisture and heat.
3. Do not use the test kit past the expiration date as indicated on the outer packaging.
4. DO NOT FREEZE.

WARNINGS AND PRECAUTIONS

Please read all of the information in the instructions for use carefully before using the test.
1. Do not swallow.
2. Do not use the test kit past the expiration date as indicated on the outer packaging.
3. Do not use test if pouch is damaged or not well sealed. Do not use any damaged test cassette or 'lollipop' saliva swab.
4. Do not open the foil pouch of the test until it is ready for immediate use.
5. Do not eat, drink or smoke prior to the test for at least 30 minutes.
6. To obtain accurate results, do not use visually bloody or overly soggy lollipop saliva swab samples.
7. Do not bite the sponge of the saliva swab.
8. Do not reuse the used test card or saliva swab. They can only be used once.
9. Inadequate sample collection, processing, storage and transport may give a false positive or a false negative result.
10. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
11. It is recommended to repeat testing within 1-2 days if there is an ongoing suspicion of infection.
12. Keep out of reach of children.
13. For ages 2 and above.
14. Children taking the test should be supervised by an adult.
15. Wear a safety mask or other face covering when collecting a saliva specimen from a child or another individual.
16. Use of Nitrile or Latex gloves is recommended when handling samples.
17. Wash hands thoroughly after handling.
18. To reduce the risk of infection spreading, discard the used test in the Biosafe Bag provided and dispose according to local regulations.

LIMITATIONS

1. Tests are for screening purposes only and any positive **results need to be confirmed by a laboratory PCR test.**
2. Test Card performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
3. Test Card performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
4. The test must be at room temperature (15~30°C/59~86 °F) for 30 minutes before use, otherwise the results may be incorrect.
5. A false negative test result may occur if the level of antigen in a sample is below the limit of detection of the test. **Results need to be confirmed by a laboratory PCR test.**
6. Failure to follow the Test Procedure may adversely affect test performance and/or invalidate the test result.
7. Reading results in less than 10 minutes may lead a false negative result whilst reading results after more than 15 minutes may lead to a false positive result.
8. Positive test results do not rule out co-infections with other pathogens.
9. Negative test results are not intended to rule in other infections.
10. Negative results should be treated as presumptive and confirmed with **a laboratory PCR test**.
11. Users should test saliva specimens as quickly as possible after the specimen has been collected.
12. If the sample volume is not enough, the test cannot be carried out successfully.

FREQUENTLY ASKED QUESTIONS

1. How accurate is the test?
The performance of the Test Card was established with 243 samples collected from symptomatic patients, within 7 days of symptom onset.

2019-nCoV Ag Saliva Rapid Test Card (Immunochromatography)	Comparative RT-PCR Test Reslt		
	Positive (+)	Negative (-)	Total
Detected Positive	110	2	112
Detected Negative	5	126	131
Total	115	128	243
Sensitivity	95.65%, 95% CI (90.22,98.13)		
Specificity	98.44%, 95% CI (94.48, 99.57).		
Accuracy	97.12%, 95% CI (94.17,98.60)		

A usability study was performed with 120 lay people. The results show that the instructions provided with the test kit made it easy for the user to understand. The test is therefore suitable for lay users. Limit of Detection : The limit of detection for the V-Chek test is 200 TCID50/mL or less.
2. Can any substances interfere with the Test?
No interference has been observed when testing the following substances: 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.
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:
- **Wuhan strain** (SARS-CoV-2 Isolate: USA-WA1/2020), can be detected by the V-Chek test at concentrations of 100 TCID50/mL or more.
- **Alpha** (B.1.1.7), **Delta** (B.1.617.2) and **Kappa** (B.1.617.1) variants can be detected by the V-Chek test at concentrations of 200 TCID50/mL or more.
Please visit www.v-chek.net.au for the most up to date variant detection information.
4. How do I know that the test was run properly?
A coloured line will appear in the control area (**C**) of the test cassette 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 1300 186 653.**
5. What should I do if the result shows positive?
- Note that you are currently suspected of COVID-19 infection.
- Contact the Customer Support Helpline on 1300 186 653.
- DO A PCR TEST FOR CONFIRMATION
- Comply with local self-isolation guidelines.
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.
- In case of suspicion, repeat the test after 1-2 days and comply with local self-isolation guidelines.
- DO A PCR TEST FOR CONFIRMATION
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 1300 186 653 with the lot number.
8. Can the test be used more than once?
No. The test can only be used once.

ASSISTANCE PERFORMING THE TEST OR INTERPRETING RESULTS

Customer Support Helpline
☎ 1300 186 653 (24 Hours, 7 Days) W: www.v-chek.net.au

LOCAL HEALTH CONTACT

Australian Capital Territory Department of Health
☎ 02 6207 7244 https://health.act.gov.au/
New South Wales Department of Health
☎ 137 788 https://www.health.nsw.gov.au/
Northern Territory Department of Health
☎ 1800 020 080 https://health.nt.gov.au/
Queensland Department of Health
☎ 134 268 https://www.health.qld.gov.au/
South Australian Department of Health
☎ 1800 253 787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health
☎ 1800 671 738 https://www.health.tas.gov.au/
Victorian Department of Health
☎ 1800 675 398 https://www.health.tas.gov.au/
Western Australian Department of Health
☎ 1800 595 206 https://www.healthywa.wa.gov.au/
TGA Contact Information For Reporting Performance And Usability Issues
1800 809 361 or 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-thediagnosis-of-sars-cov-2infection-using-rapid-immunoassays.
4. Considerations on the use of self-tests for COVID-19 in the EU/EEA. 17 March 2021.

INDEX OF SYMBOLS

	Consult Instructions For Use	2°C~30°C	Store at 2°C~30°C		Use-by date
	Manufacturer	LOT	Batch code		Do Not Reuse
IVD	In Vitro Diagnostic Medical Device	EC REP	Authorized representative in the European Community		Keep away from Sunlight
	Date of Manufacturer	Σ	Contains sufficient for <n> tests		Keep Dry
REF	Catalogue Number		Do not use if pouch is damaged		

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W: **www.v-chek.net.au**

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COVID-19 Antigen Saliva Test (Lollipop Test)

V-CHEK™

Note : Use test only one time. Test within first 7 days of symptoms. Testing by adult only or under adult supervision

INSTRUCTION VIDEO

TEST KIT

'LOLLIPOP' SALIVA SWAB

TEST CASSETTE

TEST PROCEDURE STEPS

1

Wash

⚠ IMPORTANT

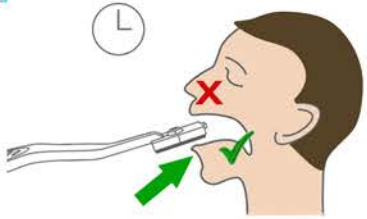
WASH HANDS WITH SOAP

2

Remove

REMOVE TEST FROM PACKAGING

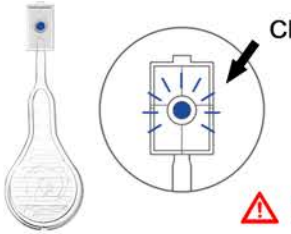
3



90 Seconds

PLACE SPONGE END IN MOUTH & **SWAB** FOR **90 SECS**

4

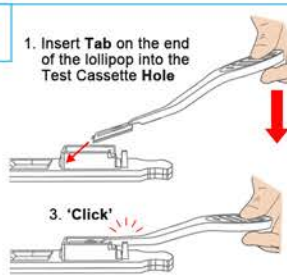


Check

⚠ IMPORTANT

REMOVE LOLLIPOP FROM MOUTH AFTER 90 SECS WHEN THE SPONGE BECOMES SOFT, AND THE INDICATOR ON THE BACK TURNS **BLUE**

5



⚠ IMPORTANT

CLICK LOLLIPOP SALIVA SWAB INTO TEST CASSETTE

6

Read result at 10 mins

Do not read after 15 mins

⚠ IMPORTANT

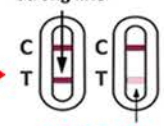
WAIT 10 MINS BEFORE CHECKING RESULTS. **NOT** AFTER 15 MINS

7

Contact Customer Support Helpline on 1300 186 653 & book a PCR test immediately

POSITIVE (+)

Strong line ⚠ IMPORTANT



Look closely!
A weak or even a faint line is still a **Positive** result!

NEGATIVE (–)

Monitor for symptoms

INVALID (X)

Re-test and call **1300 186 653** for further assistance

CHECK RESULTS AT 10 MINS. **NOT** AFTER 15 MINS. THEN TAKE ACTION IF NECESSARY!

8

Dispose & Wash

DISPOSE OF TEST IN BIOSAFE BAG PROVIDED, THEN WASH HANDS

Instructional Video : www.v-chek.net.au

24/7 Customer Support Helpline : 1300 186 653

V 1.15