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: 0693CCX001 (1 Tests/Ki), 0693CCX005 (5 Tests/Ki), 0693CCX003 (3 Tests/Ki), 0693CCS002 (20 Tests/Ki)

INTENDED USE

The COVID-19 Antigen Saliva Test is a lateral flow immunosorbent intended for the qualitative detection of nucleocapsid protein antigens 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 SARS-CoV-2 antigens in human saliva samples. When the antigen is in the sample (i.e., included in the test area (C)), the membrane will form a coloured line. Absence of this coloured line suggests a negative result.

CONTENTS OF THE TEST KIT

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

IF YOU HAVE Platzed THE BEK TEST

WHAT ELSE DO YOU NEED?

1. Timer

STORAGE

1. Store the packaged test between 2-8°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 sealed. Do not use damaged cassette test or ‘Lollipop’ saliva swab samples.
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 visibly bloody or overly soggy ‘Lollipop’ saliva swab samples.
7. Do not bite the ‘Lollipop’ saliva swab.
8. Do not reuse the 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 late phase of infection and in asymptomatic individuals.
11. It is recommended to repeat testing within 2-3 days if there is an ongoing suspicion of infection.

13. For ages 2 and above.
14. Children taking the test should be supervised by an adult.
15. Wear a safety goggle or 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 not correlate with viral culturing or quantitative RT-PCR 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 (16-36°C/60-88°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 the sample is below the limit of detection of the test. The test must 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 to a false negative result whereas reading results after 15 minutes may lead to a false positive result. Positive test results do not rule out co-infections with other pathogens.
8. Negative test results are not intended to rule out infections.
9. Negative results should be treated as presumptive and confirmed with a laboratory PCR test.
10. Users should test saliva specimens as quickly as possible after the specimen has been collected.
11. 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, with 70% sensitivity and 100% specificity.

2. What is a ‘Lollipop’ Saliva Swab?
   A Saliva Swab is a device used to collect saliva samples for the COVID-19 Antigen Saliva Test. It consists of a ‘Lollipop’ swab, which is inserted into the mouth to collect saliva.

3. What is the limit of detection of the test?
   The limit of detection of the V-Chek test is 100 TCID50/mL or less.

4. Can substances interfere with the Test?
   No interference has been observed when testing the following substances: Whole Blood, Tissue, Saliva, Nasopharyngeal and Nasal Swabs, and other body fluids.

5. How do I know 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. If you run a new test or call the Customer Support Helpline on 1300 186 653.

6. What should I do if the result shows positive?
   - Contact the Customer Support Helpline on 1300 186 653.
   - Do a PCR TEST FOR CONFIRMATION.
   - Comply with local self-isolation guidelines.

7. 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.

8. Do a PCR TEST FOR CONFIRMATION
   - Positive result by PCR confirms COVID-19.
   - Negative result by PCR is not considered a final diagnosis.

9. 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
1300 658 658

New South Wales Department of Health
137 788

Northern Territory Department of Health
1800 080 800
https://www.nt.gov.au/

Queensland Department of Health
134 268

South Australian Department of Health
1800 253 787

Tasmanian Department of Health
1800 671 738

Victoria Department of Health
1800 575 309

Western Australian Department of Health
1800 555 206

TGA Contact Information For Reporting Performance And Usability Issues
1800 639 261 or info@tga.gov.au

REFERENCES

4. Validation using rapid immunodiagnostic assays.

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W: www.v-chek.net.au

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COVID-19 Antigen Saliva Test (Lollipop Test)

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

1. Wash hands with soap.

2. Remove test from packaging.

3. Place sponge end in mouth & swab for 90 secs.

4. Insert tab on the end of the lollipop into the test cassette hole.

5. Push down until lollipop "clicks" into place.

6. Read result at 10 mins. Do not read after 15 mins.


8. Dispose & Wash.

Check results at 10 mins. Do NOT after 15 mins. Then take action if necessary.

POSITIVE (+) - Strong line
NEGATIVE (-) - Monitor for symptoms
INVALID (X) - Re-test and call 1300 186 653 for further assistance

Dispose of test in bio-safe bag provided, then wash hands.

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

24/7 Customer Support Helpline: 1300 186 653