Well Biotech Australia

Orawell COVID-19 Ag
Rapid Saliva Test Device (Self-test)

FOR PROFESSIONAL IN VITRO DIAGNOSTIC USE ONLY.

INTENDED USE

COVID-19 Ag Rapid Saliva Self-Test Device is a rapid chromatographic immunoassay for the qualitative detection of N antigen from SARS-CoV-2 present in human saliva within the first 7 days of symptom onset. This test is for self-testing purposes, as an aid to diagno-sis of SARS-CoV-2 infection in patient.

This test is authorised for home use in individuals:

- **Aged 12 years or older**
- **Aged 2 – 11 who will have their test supervised by a parent or legal guardian**
- **Who have experienced covid like symptoms within the last 7 days**

SUMMARY

Coronavirus is a single-stranded positive-sense RNA virus with an envelope of about 80 to 120 nm in diameter. Its genetic material is the largest of all RNA viruses and is an important pathogen of many domestic animals, pets, and human diseases. It can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. The 2019 new coronavirus, or "SARS-CoV-2 (COVID-19)" named by the World Health Organization can cause pneumonia epidemic.

The detection results of this kit are for clinical reference only. The result of this test should not be the sole basis for the diagnosis; confirmatory testing is required.

PRINCIPLE

The COVID-19 Ag Rapid Saliva Test Device uses double antibody sandwich immunoassay. The NC membrane pre-immobilized with monoclonal antibodies against SARS-CoV-2 antigen and anti-mouse polyclonal antibodies, and the colloidal-gold conjugated with monoclo-nal antibodies specific to SARS-CoV-2 antigen.

If SARS-CoV-2 antigen present in the sample, a complex formed between the anti-SARS-CoV-2 conjugate and the antigen will be caught by the specific anti- SARS-CoV-2 monoclonal coated on the re-gion. Results appear in 10 to 20 minutes in the form of a red line that develops on the strip.

Whether the sample contains the SARS-CoV-2 antigen or not, the solution continues to migrate to encounter another reagent (an anti-mouse IgG antibody) that binds the remaining conjugates, thereby producing a red line on the region C.

KIT CONTENT

Single pack
1) 1x Test device (individually packed in a foil pouch with desiccant).
2) 1x Instruction for use.
3) 1x Biohazard bag.

5 pack
1) 5x Test device (individually packed in a foil pouch with desiccant).
2) 5x Instruction for use.
3) 5x Biohazard bag.

20 pack
1) 20x Test device (individually packed in a foil pouch with desiccant).
2) 5x Instruction for use.
3) 20x Biohazard bag.

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

PRECAUTIONS

- Use the test kit once only. Do not reuse the test strip.
- Remove the test device from the sealed pouch only when you are ready to perform the test.
- Do not use the test kit if the pouch is damaged.
- In the event of a spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.
- Use only the components of this test kit.
- Inadequate or improper sample collection may lead to inaccurate or false results.
- If you suspect the presence of blood on the swab, discard the swab and repeat the test with a fresh one.
- Avoid contact with skin and eyes. In case of accidental contact, rinse well in order to avoid skin irritations. In case of concerns, consult your doctor.
- Keep the test kit away from children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
- Do not use any of the test components in the body with the exception of the swab included in the kit. Do not swallow any of the components.
- This test is for presumptive screening only. Please consult a doctor to discuss your test result and to find out whether additional tests are needed. Please also consult a doctor if you have any concerns about your health, if you are experiencing prolonged symptoms, or if your symptoms are worsening.
- If your test result is positive you must have a confirmatory laboratory PCR test. Consult your doctor for any follow-up clinical care.
- Repeat testing is recommended (e.g. within 1-3 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.
- Even if your test result is negative, continue to observe all applicable hygiene and safety measures. Even with a negative result, you may still be infectious. If you are showing symptoms you must seek immediate further testing by a laboratory PCR.
- Dispose of the kit components in your household waste (not recycling) or according to your local guidelines. Remaining liquid in the tube should not be released into the drainage system or water bodies.

STORAGE AND STABILITY

Store the COVID-19 Ag Rapid Saliva Test Device at 2-30°C. Do not freeze. All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.

LIMITATIONS

- Failure to follow the testing steps may give inaccurate results.

  This COVID-19 Antigen Rapid Test is for self-testing in vitro diagnostic use only.

- The results obtained with the test should be considered with other clinical findings from other laboratory tests and evaluations.

  If the test result is negative or non-reactive and clinical symptoms persist, it is because the very early infection virus may not be detected. It is recommended to test again with a new test 1-2 days later or go to the hospital to rule out infection.

- Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

- This COVID-19 Antigen Rapid Test is less reliable in the later phase of infection and asymptomatic, it is recommended to use the test within the first 7 days of symptom onset.

- Negative results may not mean that a person is not infectious and if symptoms are present you must seek immediate further testing Via a laboratory PCR Method.

- A negative result does not rule out infection with another type of respiratory virus.

- The test is for one time use only, do not reuse the test.
  Tests for children and young people should be supervised by an adult or a guardian.

- Please keep out of reach of children.

- If a Positive result is given the immediate requirement is to present to your nearest Covid Testing Clinic for a confirmatory a laboratoryPCR Test. For advice on how to seek medical help or get tested for coronavirus (COVID-19) Please refer to these Instructions for use to see your state or territory contact details.
- Contact the TGA to report poor performance or 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

PERFORMANCE CHARACTERISTICS

CLINICAL EVALUATION

Clinical evaluation was performed to compare the results obtained by COVID -19 Ag Rapid Saliva Test Device and PCR. The results were summarized below:

TABLE 1 : COVID AG RAPID SALIVA TEST DEVICE VS. PCR

		COVID Ag Rapid Saliva Test Device		Total Result
		+	-	
PCR	+	142	8	150
	-	0	200	200
Total Results		142	208	350

Relative sensitivity: 94.74% (95%CI89.83%~97.27%)
Relative specificity: 100% (95%CI 98.12%~100%)
Overall agreement: 97.90% (95%CI 95.56%~98.84%)
CI: Confidence Interval

CROSS REACTION:

Cross reactivity with the following organisms has been studied. Positive samples of the following organisms have no cross reactivity with the COVID-19 Antigen Saliva Test Kit. Adenoviruses, Epstein-Barr virus, Enterovirues, Echovirus 6, HCoV viruses, Bordetellas, Candida albicans, Chlamydia pneumoniae, Group C Streptococcus, Haemophilus influenzae, Legionella pneumophila, MERS- coronovirus, SARS-coronavirus, Human metapneumovirus, Influenza A (H1N1)pdm09, Influenza viruses, Novavirus, Parainfluenza viruses, Respiratory syncytial viruses, Rhinovirus B52, Mycoplasma pneumoniae, Mycobacterium tuberculosis, Staphylococcus, Streptococcus. COVID-19 Antigen Saliva Test Kit might have cross-reactivity with human coronavirus HKU1 and SARS-CoV because they have high homology to the SARS-CoV-2

MICROBIAL INTERFERENCE:

Microorganism: Streptococcus hemolyticus, Pseudomonas aeruginosa, Staphylococcus aureus, Escherichia coli, Candida albicans, Aspergillus niger.

The results show that microorganism listed above has no microbial interference on the negative and positive test results, and these substances do not cross-react with COVID-19 Antigen Rapid Saliva Test Device.

ENDOGENOUS INTERFERENCE:

The COVID -19 Ag Rapid Saliva Test Device was evaluated with endogenous interference substances.Chloraseptic (Menthol/Benzocaine) (1.5 mg/mL), Naso GEL (NeilMed) (5 % v/v), CVS Health Nasal Drops (Phenylephrine) (15 % v/v), Afrin (Oxymetazoline) (15 % v/v), CVS Health Oxymetazoline (15 % v/v), CVS Health Nasal Spray (Cromolyn) (15 % v/v), Zicam (5 % v/v), Homeopathic (Alkalol) (1:10 dilution), Sore Throat Phenol Spray (15 % v/v), Tobramycin (4 µg/mL), Mupirocin (10 mg/mL), CVS Health Fluticasone Propionate (5 % v/v), Tamiflu (Oseltamivir Phosphate) (5 mg/mL), Whole Blood (4 %), Mucin (0.5 %). The results show that endogenous interference substances listed in above table has no inference effect on the negative and positive test results, and these substances do not cross-react with COVID-19 Antigen Rapid Saliva Test Device.

LIMIT OF DETECTIONS:

- The limit of detection of this device is confirmed as 60 TCID50/mL for BetaCoV/Wuhan/IPBCAMS-WH-01/2019.
- The limit of detection of this device is confirmed as 100 TCID50/mL for SARS-CoV-2 variant (Alpha, Beta, Gamma and Delta)

DETECTION AGAINST VIRAL VARIANTS:

- This test is not affected by variants Alpha, Beta, Gamma, Delta, Kappa, Epsilon, and Lambda.

MANUFACTURED BY:

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Australian Sponsor:
Motion One Pty Ltd
1800 952 915 (24 hours | 7 days)
G7, 283 Alfred St, North Sydney, NSW, 2060
info@wellbiotech.com.au

IMPORTANT CONTACTS

In the event you are experiencing problems with the test, please contact Well Biotech Australia. Additionally, you may wish to report poor performance or usability issues directly to the Therapeutic Goods Administration (TGA) via the Medical Device Incident Reporting scheme, email iris@tga.gov.au or call 1800 809 361.

To contact your local state/territory health department click on the following link:
https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments
Local state and territory health departments

Contact details and websites of the local state and territory health departments:

- **Australian Capital Territory Department of Health**
  General Enquiries: 02 5124 9213
  Coronavirus helpline (8am to 8pm daily) : 02 6207 7244
  Website: https://health.act.gov.au/
- **New South Wales Department of Health**
  General enquiries: 1300 066 055
  Coronavirus hotline (Service NSW, 24/7): 137 788
  Website: https://www.health.nsw.gov.au/
- **Northern Territory Department of Health**
  General enquiries: 08 8922 8044
  Coronavirus hotline (National helpline): 1800 020 080
  Website: https://health.nt.gov.au/
- **Queensland Department of Health**
  General enquiries: 13HEALTH or 13 432 584
  Coronavirus hotline: 134COVID or 134 268
  Website: https://www.health.qld.gov.au/
- **South Australian Department of Health**
  General enquiries: 1300 232 272
  Coronavirus hotline (9am to 5pm daily): 1800 253 787
  Website: https://www.sahealth.sa.gov.au/
- **Tasmanian Department of Health**
  General enquiries: 1300 135 513
  Public Health Hotline (coronavirus): 1800 671 738
  Website: https://www.health.tas.gov.au/
- ***Victorian Department of Health***
  Department of Health and Human Services: 1300 650 172
  Victorian coronavirus hotline (24/7) : 1800 675 398
  Website: https://www.dhhs.vic.gov.au/
- **Western Australian Department of Health**
  General enquiries 08 9222 4222
  Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri)
  Website : https://www.healthywa.wa.gov.au/

BEFORE TESTING, SCAN THE QR CODE TO WATCH THE HOW TO USE VIDEO, OR VISIT
https ://wellbiotech.com.au/covid-19-rapid-test-co-07/

Customer support:1800 952 915
Available 24 hours, 7 days

SYMBOLS

Symbol	Meaning
	Consult instruction for use
IVD	In-Vitro Diagnostic Medical Device
	Manufacturer
LOT	Batch code
	Caution, consult accompanying documents
	Keep away from sunlight
	Do not reuse
	Temperature Limitation
	Use by date
	Production Date
	Contains sufficient for <n>test
EC REP	Authorized representative in the European Community
CE	Meet the requirements of EC Directive 98/79/EC

Effective Date: 2021.05.11

TEST PROCEDURE

BEFORE STARTING

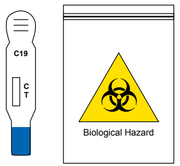
Before collecting oral fluid, nothing is to be placed in the mouth including food, drink, gum, or tobacco products for at least 10 minutes prior to collection.

Wash or sanitise your hands.

Make sure they are dry before starting.

MATERIALS PROVIDED

1) Test kit
2) Biohazard Specimen Bag



1. PREPARE FOR THE TEST

Check the expiration date on the box. Do not use if the kit has expired.

Ensure the kit is at room temperature for at least 30 minutes prior to use.

Open the box carefully as it will be used in a later step.

Do not open individual components until instructed.

Note: A time device (clock, timer, etc) is required, but not provided.

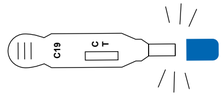
2. COLLECT SAMPLE

Deeply cough 3 - 5 times

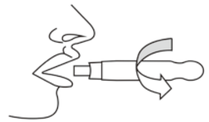
Note: Wear a face mask or cover your mouth and nose with a tissue when you are coughing and keep distance with other people.

3. COLLECT SAMPLE

3A) Pull the blue cap off gently by holding the sides to expose the collection pad.



3B) Hold the top portion of the device and place the collection pad into the mouth.



3C) Rub the collection pad against the cheek and tongue gently in a circular motion 10 times. Then place the collection pad in the mouth for about 1~2 minutes, check to see if the Cline has shown up in the C region. If not, please repeat until a C line is visible.

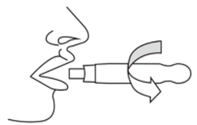


Fig. A Gently rub the collection pad against each cheek several times.

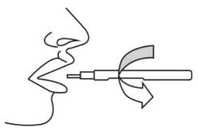


Fig. B Gently rub the collection pad on top of the tongue.

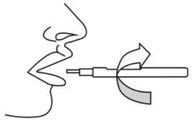


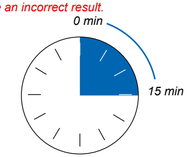
Fig. C Place the collection pad underneath the tongue.

4. WAIT FOR RESULTS

Do not touch the Test Device during this period

Read the result at 15 minutes.

Do not read the results before15 minutes or after 20 minutes, it may be an incorrect result.



5. READ TEST RESULT

POSITIVE RESULT

One coloured line should be in the control region (C) and another coloured line should be in the Test region (T).

***Note: The intensity of the colour in the test line region (T) will vary based on the amount of SARS-(CoV-2 antigen present in the sample. So any shade of colour in the test region (T) should be considered positive.** A positive result means it is very likely you have COVID-19, but the positive samples should be confirmed to reflect this. Immediately go into self-isolation in accordance with the local guidelines and immediately contact your general practitioner/doctor or the local health department in accordance with the instructions of your local authorities.*

Your test result will be check by a laboratory PCR confirmation test and you will be explained the next steps.

For ALL Positive results a Confirmatory PCR test by a laboratory is required. Please contact your local COVID Help Line on the reverse side of these instructions or, please contact our helpline on 1800 952 915 (24 hours | 7 days).

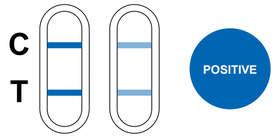


Fig. D Positive Result

NEGATIVE RESULT

No apparent coloured line appears in the test line region (T)

You are unlikely to have COVID-19. However, it is possible for this test to give a negative result that is incorrect (a false negative) in some people with COVID-19. This means you could possibly still have COVID-19 even though the test is negative.

If you experience symptoms such as headaches, migraines, fever, loss of sense of smell or taste, contact the nearest medical facility according to the rules of our local authority. In addition, you can repeat the test with a new test kit. In case of suspicion repeat the test after 1-2 days, as the corona virus cannot be precisely detected in all phases of an infection.

Even with a negative test result, distance yourself and hygiene rules must be observed, migration/traveling, attending events, etc, you should follow your local COVID guidelines/ requirements.

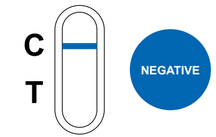


Fig. E Negative Result

INVALID RESULT (TEST DID NOT WORK)

Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test or contact our COVID-19 test centre.

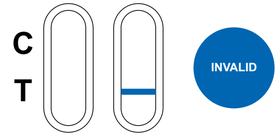
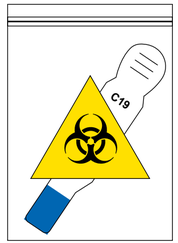


Fig.F Invalid Result

6. DISPOSE THE TEST KIT

6A) After the test is complete, place all the components into the plastic Bio-Safety bag (supplied)

6B) Dispose according to local regulations



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