The COVID-19 Ag Rapid Saliva Test Device uses double antibody chromatographic immunoassay for the qualitative detection of SARS-CoV-2 antigens in human saliva within the first 7 days of symptom onset.

SUMMARY

- The COVID-19 Ag Rapid Saliva Test Device is a rapid diagnostic test for the qualitative detection of SARS-CoV-2 antigens in human saliva.

FOR SELF-TESTING:


INTENDED USE

The COVID-19 Ag Rapid Saliva Test Device is in a rapid diagnostic immunoassay for the qualitative detection of SARS-CoV-2 antigens in human saliva within the first 7 days of symptom onset. This test is for self-testing purposes, as an aid to diagnosis of SARS-CoV-2 infection.

The test is authorized for use in individuals:

- Aged 2 – 11 who will have their test supervised by a parent or legal guardian.

- Who have experienced symptoms likely to be caused by this infection within 7 days of their onset.

Whether the sample contains the SARS-CoV-2 antigen or not, the result will show up as a red line on the region C. Therefore, it is recommended to perform this test prior to entering any restricted areas.

KIT CONTENT

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

REQUIRED MATERIALS BUT NOT PROVIDED

- Timer

PRECAUTIONS

- Use the test only once. Do not use the test strip.
- Remove any test components from the test kit within 24 hours.
- Do not use the test kit if the packaging is damaged.
- In the event of a spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.

STABILITY AND STORAGE

- Store the COVID-19 Ag Rapid Saliva Test kit at 2 – 8°C. Do not freeze.
- All reagents are stable until the expiration dates marked on their respective packaging.

LIMITATIONS

- Failure to follow the testing steps may give incorrect results.
- The COVID-19 Ag Rapid Saliva Test kit is for self-testing in vitro diagnosis only.
- The results obtained with the test should be considered with other evidence obtained from clinical examination, epidemiological investigations and laboratory tests.
- The test kit may show a negative result when there is a deficiency in the antigen and symptomatic sample.
- The test kit is designed for one-time use only, do not reuse the test kit.

CROSS REACTION:

- Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.
- Cross-reactivity with the following organisms has been studied. Positive results of COVID-19 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

MICROBIAL INTERFERENCE:

- Contact the TGA to report poor performance or usability issues in the test kit.

FDA/FOOD ADVISORY INTEREST:

- Food and Drug Administration has evaluated the potential contamination of food in dry saliva samples with the COVID-19 Ag Rapid Saliva Test kit.

LIMIT OF DETECTIONS:

- Limit of detection of this device is 0.13 TDD50 for SARS-CoV-2;

DETECTION AGAINST VIRAL VARIANTS:

- The COVID-19 Ag Rapid Saliva Test kit is evaluated with endolysates of SARS-CoV-2 variant (Alpha, Beta, Gamma and Delta)

CONTACT INFORMATION:

- Australian Sponsor: Motion One Pty Ltd
- Tel: +86-519-80191660
- MANUFACTURED BY:
- Orawell COVID-19 Ag Rapid Saliva Test Device
- Website: https://www.owasan.com

OTHER SOURCES:

- Western Australian Department of Health: Website: https://www.health.wa.gov.au/
**TEST PROCEDURE**

**BEFORE STARTING**

Before collecting a saliva or nasal sample, please ensure:
- The test kit is at room temperature for at least 30 minutes prior to use.
- The kit is not expired.
- Check the expiration date on the box. Do not use if the kit has expired.

**MATERIALS PROVIDED**

- Test kit
- Biohazard Specimen Bag
- Test kit with a test device, tongue depressor, and a mouth swab
- Deeply cough 3-5 times.
- Gently rub the collection pad on top of the tongue.
- Pull the blue cap off gently by holding the sides to expose the collection pad.
- Hold the test device with your non-dominant hand and place the collection pad into the mouth.
- Press firmly into the cheeks to expose the collection surface. Try to keep it location for about 3-5 minutes.
- Place the collection pad underneath the tongue.
- Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.
- Make sure they are dry before use.

**COLLECT SAMPLE**

1A) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1B) Press firmly into the cheeks to expose the collection surface. Try to keep it location for about 3-5 minutes.

1C) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1D) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1E) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

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1H) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1I) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1J) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1K) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1L) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1M) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1N) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1O) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1P) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1Q) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1R) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1S) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1T) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1U) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1V) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1W) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1X) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1Y) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

1Z) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

2) Collect oral fluid, nothing is to be placed into the mouth including food, drink, gum, or tobacco products to be placed in the mouth including any substances such as mouthwash.

**WAIT FOR RESULTS**

Read the result paper. Follow the protocol for the test kit.

**POSITIVE RESULT**

A positive result means it is very likely you have COVID-19 even though the test is negative. 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.

**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 the infection.

**INVALID RESULT (TEST DID NOT WORK)**

Dispose of the test kit. Please contact our COVID-19 test helpline on 1800 952 915 (24 hours, 7 days).

**DISPOSE THE TEST KIT**

- After the test is complete, place all the components into the plastic Bio-Safety bag (supplied).
- Dispose in your house hold waste.