COVID-19 Antigen Saliva Test Kit 

1. INTENDED USE 
The COVID-19 Antigen Saliva Test Kit is an in vitro immunoassay that detects SARS-CoV-2 antigen, beta, gamma, kappa and delta. The kit is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from human saliva samples collected from individuals suspected of having COVID-19 within the first 7 days of symptom onset. The COVID-19 Antigen Saliva Test Kit is intended for use by laypersons and enables self-testing at home.

The test identifies SARS-CoV-2 viral nucleoprotein antigen. Antigen is generally detectable in saliva samples during the acute phase of infection.

2. PRINCIPLE 
The COVID-19 Antigen Saliva Test Kit detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti-SARS-CoV-2 antibodies are immobilised on the test strip of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to colloidal particles are immobilised on the conjugated pad. A sample is added to the extraction buffer in the base, which is optimized to release the SARS-CoV-2 antigens from the specimen. During testing, target antigens, if present in the saliva samples, will be released into the extraction buffer individually packed in the kit. The extracted antigens will bind to anti-SARS-CoV-2 antibodies conjugated to colloidal particles. As the specimen migrates along the strip by capillary action and interacts with reagents on the membrane, the complex will be captured by the anti-SARS-CoV-2 antibodies at the test region. Excess colloidal particles are captured at the internal control region. The presence of a colored band in the test region indicates a positive result for the SARS-CoV-2 viral antigens, while its absence indicates a negative result. A colored band at the control region serves as a procedural control, generally indicating that the proper volume of specimen has been added and membrane wicking is working.

3. MATERIALS 

Materials Provided

• 2 Pack: 2 Individual packaged test
• 1 Package insert
• 2 Waste bags
• 5 Pack: 5 Individual packaged test
• 1 Package insert
• 5 Waste bags

Materials Required but Not Provided
Clock, timer, or stopwatch

4. PRECAUTIONS

For In Vitro Diagnostic Use Only

• Each device is for single use only and cannot be reused
• DO NOT eat, drink, smoke, brush teeth, or chew gum for 30 minutes before collecting saliva. DO NOT swallow. Avoid chocking being cues when inserting the sponge in the mouth.
• Keep out of the reach of children. Children 2-15 years of age should be tested by an adult. Children under 2 years of age should be assisted by an adult. Do not use this test on children under 2 years of age.
• Use a separate test for each person
• This test is for human use only
• Read the Package Insert prior to use.
• Directions should be read and followed carefully.
• Do not use kit or components beyond the expiration date.
• Do not use if package is damaged or open.

Test devices are packaged in foil pouches that exclude moisture during storage. Inspect each foil pouch before opening. Do not use devices with holes in the foil or pouch that may compromise integrity. Trivial results may occur if test reagents or components are improperly stored.

Do not use the kit when any component including test device, protector, base, package insert is missing.

Failure to bring specimens and reagents to room temperature before testing may decrease assay sensitivity, or may lead to false positive results. Inaccurate or inappropriate specimen collection, storage, and transport may also yield false test results.

The buffer components in the base include salts, surfactants, preservative and sodium azide and water is the solvent. Avoid skin or eyes contact with buffer.

Keep the collector clean. Do not touch the collector and make sure it does not touch any surfaces before use. Place the swab in the base immediately after using it. Place immediately in extraction buffer.

COVID-19 Antigen Saliva Test Kit could detect SARS-CoV-2 variant alpha, beta, gamma, kappa and delta.

5. STORAGE AND STABILITY

Store the COVID-19 Antigen Saliva Test Kit at 2-30°C when not in use.

DO NOT FREEZE.

DO not use kit or components beyond the expiration date.

6. QUALITY CONTROL

Internal Procedural Controls

The COVID-19 Antigen Saliva Test Kit has built-in (procedural) controls. Each test device has an internal standard to ensure proper sample flow. The user should confirm that the colored band located at the “C” region is present before reading the result.

7. LIMITATIONS OF THE TEST/WARNINGS

1. The COVID-19 Antigen Saliva Test Kit is for in vitro diagnostic use and should only be used once for the qualitative detection of the SARS-CoV-2 antigen. The brightness of a positive band should not be evaluated as “quantitative or semi-quantitative.”

2. Children below 15 years old need adult supervision.

3. Failure to follow the TEST PROCEDURE and RESULT INTERPRETATION may adversely affect test performance and/or invalidate the test result.

4. If the result is positive, one must still confirm the results immediately by a laboratory RRT-PCR test and seek follow-up clinical care.

5. Positive results do not rule out bacterial infection or co-infection with other viruses and the agent detected may not be the definite cause of disease.

6. A positive result does not necessarily mean the patient is infected.

7. Negative results do not preclude SARS-CoV-2 infection and the person not being infected. Therefore, the results should be confirmed via a laboratory RRT-PCR test especially if the person has symptoms and should seek follow-up clinical care.

8. Even if the result is negative, you still need to observe all protective and hygienic measures.

9. If there is ongoing suspicion of infection or high risk of infection in the area, repeat testing within 1-3 days is recommended.

10. The tests are less reliable in the later phase of infection and in asymptomatic individuals.

11. False negative results may appear if testing is not performed within the first 7 days of symptom onset.

12. There may be false negatives due to new unknown variants of SARS-CoV-2, prior to validating results.

8. PERFORMANCE

Detection Limit: The detection limit for the COVID-19 Antigen Saliva Test Kit is less than 32 TCID50/mL.

Clinical Evaluation: The COVID-19 Antigen Saliva Test Kit was established with 248 specimens and collected from individual symptomatic patients who were suspected of COVID-19. FDA EUA RT-PCR assay for the detection of SARS-CoV-2 was used as the comparator method for the study. The test was evaluated in 1499 participants, with 139 positive results.

Table: COVID-19 Antigen Saliva Test Kit

<table>
<thead>
<tr>
<th>Sample</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19 Antigen Saliva Test Kit</td>
<td>40</td>
<td>2</td>
<td>42</td>
</tr>
</tbody>
</table>

Relative Sensitivity: 88.8% (95.9% - 91.9%)  Relative Specificity: 99.0% (94.0% - 99.0%)
Overall Agreement: 99.2% (98.1% - 99.0%) 95% Confidens Interval

Layerson study was evaluated with 106 layoffs from different age and different education to establish the performance and stability of COVID-19 Antigen Saliva Test Kit in a self-testing environment. The laypersons did the test while being observed by trained personnel. The result shows the COVID-19 Antigen Saliva Test Kit is sensitive and reliable. The results showed that the labeling provided with the test kit was comprehensive for its intended population, the ease of use was suitable for its intended population.

Cross-reactivity: 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: Influenza A, Influenza B, Enterovirus, Echovirus 6, HCV viruses, Bordetella, Candida albicans, Chlamydia pneumoniae, Group C Streptococcus, Haemophilus influenzae, Legionella pneumophila, MERS- coronaviruses, SARS-coronavirus, Human metapneumovirus, Influenza A (H1N1) pdm09, Influenza viruses, Novariviruses, Parainfluenza viruses, Respiratory syncytial viruses, Rhinovirus B52, Mycoplasma pneumoniae, Mycobacterium tuberculosis, Staphylococcus and Streptococcus, COVID-19 Antigen Saliva Test Kit may have cross-reactive with human coronavirus HKU1 and SARS-CoV because they have high homology to the SARS-CoV-2 Interfering Substances: The Interfering substances, naturally present in respiratory specimens or may be artificially introduced into the respiratory tract, were evaluated. None of them were found to affect the test performance of the COVID-19 Antigen Saliva Test Kit.

9. LITERATURE REFERENCES
3. OTC nasal sprays, 3 OTC mouthwashes, 3 OTC throat drops, 4- acetylsalicylic acid, Adaminamantane, Acetylsalicilic acid, Albuterol, Chlorpheniramine, Dexamethasone, Desomethylpropranolol, Diphenhydramine, Doxazosin Mesylate, Flumazenil, Flunisolide, Guaiacol glyceryl ether, Mucin, Mupirocin, Omeprazole, Phenylphenone, Phenypropanolamine, Omeprazole, Polyformaldehyde, Polyvinyl alcohol, Tobramycin, Trimethoprin, Whole blood, Zanamivir

Customer Support Helpline
1300 728 439              9am-7pm (AEST) ... Device 
Incident Report on email iris@tga.gov.au or
call 1800 809 361         or                https://www.tga.gov.au/

New South Wales Department of Health 
Northern Territory Department of Health 
Queensland Department of Health 
South Australian Department of Health 
Tasmanian Department of Health 
Victoria Department of Health 
Western Australian Department of Health 

Contact Information 
Contact TGA to report an issue via the Users Medical Device Incident Report on email iris@tga.gov.au or call 1800 809 361 or https://www.tga.gov.au/
COVID-19 Antigen Saliva Test Kit Self Test Instruction Guide

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

Version 2
21.10.21

1. **Do Not** eat, drink, smoke, brush teeth or chew gum 30 mins before test

2. Wash hands before test

3. Remove test from package

4. Take saliva collector out of base

5. Remove the protector

6. Deeply cough 4 times into your mouth

7. Place collector on top, under or side of tongue for 2 mins

8. Take collector from mouth and push vertically into the base

9. Top edge of base to be in middle of supporting ring

10. Read results at 15 mins

11. Do not read after 30 mins

12. Put test in disposal bag and dispose into household waste bin

**Positive**
Take a PCR laboratory test immediately and contact your health provider

Strong line

Weak or even a faint line

**Negative**
Monitor for symptoms

**Invalid**
Invalid if no control line

Make sure to push the collector into the base.
Re-test and call 1800 728 439 for further assistance