INSTRUCTIONS FOR USE

1. Preparing for the test

- Prepare your test space by cleaning and drying a flat, well-lit surface, such as a table or countertop.
- Blow your nose with a tissue and throw it away.
- Wash your hands thoroughly and dry them.

2. Collect and prepare sample

- Open one test and remove all the contents from the holder.
- Verify that the contents are all included and undamaged.
- Open the pouch labeled “Buffer tube and Nozzle”.
- Flip the empty holder over to use as a tube rack.
- Carefully peel off the seal of the buffer tube.
- Place the open tube in the tube rack.
- Remove the swab by peeling back at the “Peel here” label. Only touch the handle of the swab.
- Place the fabric tip of the swab inside the nostril, about 2 cm into the nose. DO NOT insert the swab any deeper if you feel strong resistance or pain. Rotate the swab inside the nostril at least 5 times, pressing against the nasal wall.

3. Test the sample

- Open the pouch labeled “COVID-19 Ag Self Test” and remove the cassette. Lay it on the clean, flat surface.
- Hold the buffer tube over the cassette and slowly add 3 drops of the liquid into the sample well (S) to avoid forming bubbles. Discard the buffer tube into the waste bag.
- Using the same swab, repeat the process in the other nostril.
- Remove the buffer tube from the rack, and insert the fabric tip of the swab into the tube. Swirl the swab in the liquid at least 5 times.
- Squeeze the tube against the submerged swab at least 5 times.
- Lift the swab out of the liquid and squeeze the tube against the fabric tip to remove excess fluid from the swab. Remove the swab from the buffer tube.
- Insert the nozzle firmly into the tube while holding the tube with your other hand.

4. Read test results

- If you are testing more than one sample, always clean the surface and wash your hands between each test.
- DO NOT turn or invert the tube during this step.
- Do not touch your cheeks, teeth, gums or any other surfaces with the fabric tip of the swab, or it might contaminate your sample.
- Immediately start timing 15 minutes and wait.

- If the Control (C) line develops: Only the Control (C) line develops. You are likely not infectious at the time the test was taken. It does not guarantee that you do not have coronavirus.
- If both Control (C) and Test (Ag) lines develop: A positive result means that you are very likely infected with coronavirus and could infect others. Contact your State or Territory Coronavirus testing services to get a laboratory PCR test.
- If the Control (C) line does not develop: There was a testing error. Read the procedure instructions and repeat the test with a new test.

5. Dispose of the test kit

- Immediately discard the waste bag.
- Do not use the kit if it’s expired or the sealed packaging is damaged.

- If you stored the kit in an area colder than 15°C, leave it at room temperature for 30 minutes before starting the test.
- Store the test kit at room temperature or in a cool, dry place (2°C-30°C). Keep the kit away from direct sunlight and do not store it in a freezer.
- Use the test kit at room temperature (15°C-30°C).

- Hotline 1800 241 881
- Operating hours: Monday - Sunday (9am - 7pm)
OnSite COVID-19 Ag Self Test

Instructions for Use

1. Critical Performance

The performance of the COVID-19 Ag Self Test was evaluated by both professional testing and by self-testing. In the self-testing study, the COVID-19 Ag Self Test correctly identified 100% (CI: 93.0% - 100%) of infected study participants. In the professional performance study, the test correctly identified 96.6% (CI: 91.6% - 98.7%) of the infected participants, and 100% (CI: 95.0% - 100%) of infected participants with a relatively high viral load (CI ≤ 30). Individuals with a high viral load are considered to be at higher risk of being infectious and transmitting the virus to others.

In both studies combined, the relative sensitivity of the COVID-19 Ag Self Test was 97.6% (CI: 94.1% - 99.4%) and the relative specificity was 99.0% (CI: 98.4% - 99.9%). The relative sensitivity of the test for patients with a relatively high viral load (CI ≤ 30) was 99.7% (97.1% - 100%). For patients tested within 48 hours post symptom onset (D0/1), the relative sensitivity was 97.3% (CI: 93.1% - 99.3%) and the relative specificity was 99.0% (CI: 96.4% - 99.9%).

2. Analytical Performance

2.1 Analytical Sensitivity (Limit of Detection, LoD)

The LoD of the OnSite COVID-19 Ag Self Test in both nasopharyngeal and nasal swab matrices was determined to be 140 TCID50/mL.

2.2 Variant detection

The OnSite COVID-19 Ag Self Test detects the Alpha (U.K.), Beta (South Africa), Gamma (Brazil), and Delta (India), and SARS-CoV-2. Interference was not observed with the following substances that were naturally present in human nasal swabs: Acetaminophen, Acetylsalicylic Acid, Mupirocin, HAMA, Biotin.

3. Analytical Specificity (Cross-Reactivity and Microbial Interference) The OnSite COVID-19 Ag Self Test was tested with the following microorganisms. There was no cross-reactivity or interference with: MERS-coronavirus NP antigen, Human coronavirus, HKU1 NP antigen, Human coronavirus OC43, Human coronavirus NL63, Adenovirus, Human Metapneumovirus (hMPV), Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Influenza A NP antigen, Influenza B NP antigen, Enterovirus, Respiratory syncytial virus (RSV), Parainfluenza 1, Streptococcus pneumoniae, Streptococcus pyogenes, Candida albicans. Pooled human nasal wash representing respiratory microbiome, Bordetella pertussis, Mycoplasma pneumoniae, Chlamydia pneumoniae, Legionella pneumophila, Mycobacterium tuberculosis, Pneumocystis jirovecii (PJP).

3.1 Interfering Substances

No interference was observed with the following substances that were naturally present in respiratory specimens or may be artificially introduced into the nasal cavity or nasopharynx: Mucin, Whole Blood, Phenylenyline, Fluconazole, Budesonide, Nasal Gel, Menthol, Benzocaine, Lopinavir, Zanamivir, Oseltamivir, Ribavirin, Peramivir, Tobramycin, Dexamethasone, Azithromycin, Amoxicillin, Acetylsalicylic Acid, Mupirocin, HAMA, Blidotin.

OnSite COVID-19 Ag Self Test is a single-use lateral flow immunassay for the qualitative detection of SARS-CoV-2 nucleocapsid antigens in nasal swab specimens from individuals suspected of COVID-19. The test is designed for use with self-collected samples within the first 7 days post-onset of symptoms, as an aid in identifying SARS-CoV-2 infection.

The OnSite COVID-19 Ag Self Test does not differentiate between SARS-CoV and SARS-CoV-2. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out other bacterial or viral infections. Individuals who test positive should confirm results with a laboratory PCR test, self-quarantine, and seek adequate care from their healthcare provider.

Negative results do not rule out SARS-CoV-2 infection and should be used only to support diagnosis. Negative results from patients with symptoms beyond 7 days should be confirmed with a PCR test.

This product is intended to be used for self-test by adults, between 18 and 12 years of age with adult supervision. Children under 12 should be tested by an adult. For in vitro diagnostic use only.

1. Read these instructions and follow the steps in order to ensure accurate results.
2. For in vitro diagnostic use.
3. The chemicals in the buffer tube (a detergent, ProClix 300, and sodium azide) are known to be non-toxic, at the levels present in the liquid. The buffer should only be used as directed: do not ingest; keep out of the reach of children; avoid contact with skin and eyes.
4. Do not overload the sample well with specimen.
5. When opening the test kit, verify that all contents are included and undamaged. Do not use the test if any contents are damaged. Use each test kit only once.
6. Blow your nose before starting the test. Too much viscus mucus might give incorrect results. The fabric tip of the nasal swab may tickle or cause mild discomfort when in use. If you feel pain, stop the test and seek advice from your healthcare provider.
7. No visible C line means that your result is invalid and there was a testing error. This could be caused by overflowing the test cassette with too much sample, or by extra mucus in the sample. You need to read the procedure instructions and repeat the entire procedure with a new kit.
8. You must read the results within the 15-20 minute window. Any result read later than 20 minutes must be repeated with a new test.
9. As long as the C line appears, any visible Ag line is a positive result. If you are not confident in the result interpretation, repeat the test.
10. This test is specific for testing nasal swab samples ONLY. Do not use other specimens to test.
11. Opening the pouch too early and exposing the cassette prematurely may lead to inaccurate results. If the steps are not followed as instructed, the performance of the test may be affected.
12. If contents of the buffer tube are spilled while performing the test, clean the spill with dish soap and water.
13. Dispose all contents of the open test kit into the waste bag, then discard the waste bag in the trash can (not recycling), or according to your local guidelines.
14. The performance of this test has only been validated for self-testing and for adults or children 12 and above, under adult supervision. Children under 12 should be tested by an adult.

OnSite COVID-19 Ag Self Test detects the Alpha (U.K.), Beta (South Africa), Gamma (Brazil), and Delta (India), and SARS-CoV-2. Interference was not observed with the following substances that were naturally present in human nasal swabs: Acetaminophen, Acetylsalicylic Acid, Mupirocin, HAMA, Biotin.

Report any performance or usability issues to TGA by e-mail (iris@tga.gov.au) or call 1800 809 361. For support services, contact your local authorities listed below.


MD Solutions Australia

MD SOLUTIONS AUSTRALASIA

Unit 1, 18–18 Enterprise St
Williamstown North VIC 3016

For Export Only, Not For Sale in the USA

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