

INSTRUCTIONS FOR USE

REF R0182CST



Scan the QR code to access IFU and procedural video

Materials Provided

Materials needed but not provided a mirror, tissues, a way to time for test results, and soap and water or hand sanitizer.

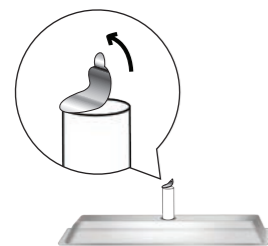
- Read these instructions before testing and follow the steps in order. Keep this guide as a reference until the entire kit is used.
 - Each test will take 10-15 minutes to set up and another 15-20 minutes to get the test results.
 - Store the test kit at room temperature or in a cool, dry place (2°C-30°C). Keep the kit away from direct sunlight and do not store it in a freezer.
 - Keep the test kit away from children.
 - Use the test kit at room temperature (15°C-30°C).
- If you stored the kit in an area colder than 15°C, leave it at room temperature for 30 minutes before starting the test.

1. Preparing for the test

- 1A** 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.

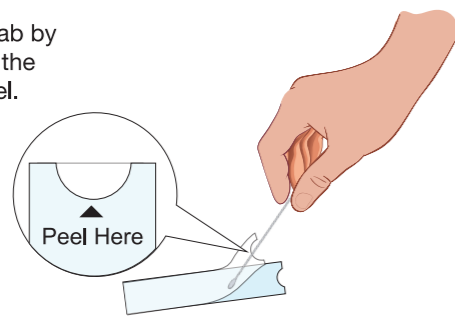


- 1B** Open one test and remove all the contents from the holder. Verify that the contents are all included and undamaged.
- Open the pouch labeled "Buffer tube and Nozzle".



- 1C** 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.

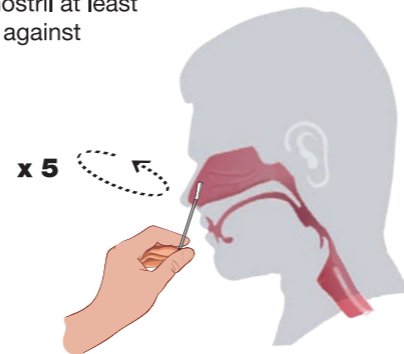
- 1D** Remove the swab by peeling back at the "Peel Here" label. Only touch the handle of the swab.
- DO NOT touch the fabric tip of the swab.



- ! If you are testing more than one sample, always clean the surface and wash your hands between each test.
- ! DO NOT touch the fabric tip of the swab with your hands.

2. Collect and prepare sample

- 2A** Insert the fabric tip of the swab into one 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.

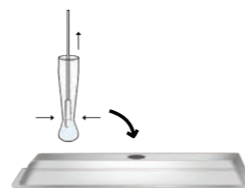


- 2B** Using the same swab, repeat the process in the other nostril.

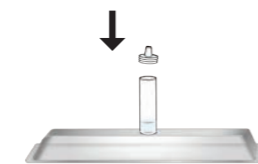
- 2C** Remove the buffer tube from the rack, and insert the fabric tip of the swab into the tube. **Swirl** the swab in the liquid at least 5 times. **Squeeze** the tube against the submerged swab at least 5 times.



- 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.



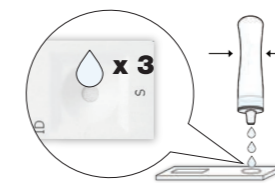
- 2D** Insert the nozzle firmly into the tube while holding the tube with your other hand.



- ! 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.

3. Test the sample

- 3A** Open the pouch labeled "COVID-19 Ag Self Test" and remove the cassette. Lay it on the clean, flat surface.
- 3B** **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.



△ Add the liquid drop by drop, and in a vertical manner.



- 3C** **Immediately** start timing 15 minutes and wait.

- ! Do not use the kit if it's expired or the sealed packaging is damaged.

4. Read test results



- Negative Result**
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.



- Positive Result**
Both Control (C) & Test (Ag) line develop. Look closely, the Ag line can be **very faint**.

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**.



- Invalid Result**
No Control (C) line develops. There was a testing error. Read the procedure instructions and repeat the entire procedure with a new test.

5. Dispose the test kit

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.



Hotline 1800 241 881
Operating hours Monday - Sunday (9am - 7pm)

OnSite® COVID-19 Ag Self Test

REF R0182CST

Instructions for Use

INTENDED USE

The OnSite COVID-19 Ag Self Test is a single-use lateral flow immunoassay 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-use 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.

WARNINGS AND PRECAUTIONS

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, ProClin 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 only once.
6. Blow your nose before starting the test. Too much viscous mucus might give incorrect results.
7. 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.
8. 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 on the sample. You need to read the procedure instructions and repeat the entire procedure with a new kit.
9. 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.
10. 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.
11. This test is specific for testing nasal swab samples ONLY. Do not use other specimens to test.
12. 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.
13. If contents of the buffer tube are spilled while performing the test, clean the spill with dish soap and water.
14. 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.
15. 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.

LIMITATIONS

1. Test results should be considered in addition to clinical correlation with patient history, other diagnostic information, and guidance from your healthcare provider.
2. This test is for the detection SARS-CoV-2 proteins only, not for any other viruses or pathogens.
3. This test is only for presumptive screening. 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.
4. A negative test result does not guarantee that you don't have coronavirus. You may have COVID-19 and still get a negative result (known as a false negative) if:
 - a. You did not perform the test accurately, such as not collecting the sample correctly or not waiting 15 minutes for your result.
 - b. The amount of virus antigen present in the sample was below the test limits.
 - c. You have had signs and symptoms of COVID-19 for longer than seven (7) days.
 - d. Tests are less reliable in the later phase of infection and in asymptomatic individuals
5. Inaccurate results may occur if the swab sample has not been properly collected and processed.
6. Inaccurate results may occur if: not enough buffer has been used into the sample well, the sample well is overloaded with buffer, or if buffer has been loaded too fast into the sample well and formed air bubbles.

7. Inaccurate results may occur if the swab specimen has not been swirled and squeezed into the extraction tube at least 5 times.
8. Inaccurate results may occur if the results are read before the 15 minutes or after 20 minutes.
9. Even if your test result is negative, continue to observe all applicable hygiene and safety measures. Even with a negative test result, you may still be infectious. If you are having prolonged symptoms, seek immediate further testing by PCR.
10. If your results are negative and you continue to have symptoms associated with COVID-19 such as fever, difficulty breathing and/or cough, you should take another test within 1-3 days.
11. If you have had signs and symptoms of COVID-19 for longer than seven (7) days, false negative results might occur. You may still have COVID-19 even though the test is negative.
12. The test detects both viable and non-viable SARS-CoV and SARS-CoV-2 antigens. Test performance depends on antigen loaded in the sample. A positive test does not rule out the possibility that other pathogens may be present.
13. OnSite COVID-19 Ag Self Test has been tested by laymen using the procedure in this Instructions for Use. Follow the steps in the Instructions for Use correctly to ensure accurate results.
14. A positive result cannot determine whether a person is infectious.

PERFORMANCE CHARACTERISTICS

1. Clinical Performance

The performance of the COVID-19 Ag Self Test was evaluated both by 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 use 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 (Ct ≤ 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 97.6% (CI: 94.1% - 99.4%) and the relative specificity was 99.0% (CI: 96.4% - 99.9%). The relative sensitivity of the test for patients with a relatively high viral load (Ct ≤ 30) was 100% (97.1%-100%). For patients tested within 7 days post symptom onset (DPSO), the relative sensitivity was 97.3% (CI: 93.1% - 99.3%) and the relative specificity was 99.0% (CI: 94.6%-100%).

Result Group	Antigen Positive/PCR Positive	Antigen Negative/PCR Negative	Relative Sensitivity (95% confidence interval)	Relative Specificity (95% confidence interval)
Self-Test	51 out of 51	98 out of 100	100% (93.0%-100%)	98% (92.9%-99.8%)
Professional Test	114 out of 118	100 out of 100	96.6% (91.6% - 98.7%)	100% (96.3%-100%)
Combined total	165 out of 169	198 out of 200	97.6% (94.1% - 99.4%)	99.0% (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), Delta (India), Eta (Nigeria), Iota (USA), Kappa (India), Lambda (Peru), P.2 (Brazil), and B.1.620 variants.

2.3 Analytical Specificity (Cross-Reactivity and Microbial Interference)

The OnSite COVID-19 Ag Self Test was tested with the following microbes. There was no cross-reactivity and interference with: MERS-coronavirus NP antigen, Human coronavirus, HKU1 NP antigen, Human coronavirus 229E, 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, Rhinovirus, Haemophilus influenzae, 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). There was cross-reactivity with SARS-CoV NP antigen.

3. 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, Phenylephrine, Fluconazole, Budesonide, Nasal Gel, Menthol, Benzocaine, Lopinavir, Zanamivir, Oseltamivir, Ribavirin, Peramivir, Tobramycin, Diphenhydramine, Dextromethorphan, 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.

<https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments>

Customer Support Helpline	1800 241 881 9am – 7pm (AEST)	MD Solutions https://www.mdsanz.com/onsiterapid
Australian Capital Territory Department of Health	Coronavirus helpline 8am to 8pm daily 02 6207 7244	ACT Health https://health.act.gov.au/
New South Wales Department of Health	Coronavirus hotline Service NSW, 24/7 137 788	NSW Health https://www.health.nsw.gov.au/
Northern Territory Department of Health	Coronavirus hotline (National helpline) 1800 020 080	Department of Health Northern Territory https://health.nt.gov.au/
Queensland Department of Health	Coronavirus hotline: 134COVID 134 268	Queensland Health https://www.health.qld.gov.au/
South Australian Department of Health	Coronavirus hotline 9am to 5pm daily 1800 253 787	SA Health https://www.sahealth.sa.gov.au/
Tasmanian Department of Health	Public Health Hotline (coronavirus) 1800 671 738	Department of Health Tasmania https://www.health.tas.gov.au/
Victorian Department of Health	Victorian coronavirus hotline (24/7) 1800 675 398	Department of Health and Human Services Victoria https://www.dhhs.vic.gov.au/
Western Australian Department of Health	Coronavirus hotline: 13COVID 8am to 6pm, Mon–Fri 1800 595 206	WA Health https://healthywa.wa.gov.au/Articles/A_E/Contact-details-for-population-public-health-units

Description of Symbols Used

 IVD	In vitro diagnostic medical device	 Manufacturer
	Do not re-use	 Date of manufacture
	Do not use if package is damaged	 REF
	Keep dry	 LOT
	Keep away from sunlight	
	Store between 2-30°C	
	Consult instructions for use	


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