# COVID-19 Antigen Nasal Test Kit Self Test

**To watch a demonstration video, scan QR code or visit**
https://www.pathdx.com.au/nasalpenhometest

## 1. INTENDED USE

The COVID-19 Antigen Nasal Test Kit is an in vitro immunoassay that detects SARS-CoV-2 variant alpha, beta, gamma, kappa and delta. The kit is for the direct and qualitative detection of SARS-CoV-2 viral nucleoprotein antigens from human nasal secretions collected from individuals suspected of having COVID-19 within the first 7 days of symptom onset. The COVID-19 Antigen Nasal 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 nasal secretions during the acute phase of infection.

## 2. PRINCIPLE

The COVID-19 Antigen Nasal Test Kit detects SARS-CoV-2 viral antigens through visual interpretation of color development. Anti-SARS-CoV-2 antibodies are immobilised on the test region of the nitrocellulose membrane. Anti-SARS-CoV-2 antibodies conjugated to colored particles are immobilized 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 nasal secretions, 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 colored 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 colored particles are captured at the internal control zone.

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
- Keep out of the reach of children. Children 2-15 years of age should be tested by an adult. Children aged 15 and over 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 pouch 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 not completely sealed. Erroneous result 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 is 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 collecting the sample.
- COVID-19 Antigen Nasal Test Kit could detect SARS-CoV-2 variant alpha, beta, gamma, kappa and delta.

## 5. STORAGE AND STABILITY

- Store the COVID-19 Antigen Nasal Test Kit at 2~30℃when not in use.
- DO NOT FREEZE.
- **D**o not use kit or components beyond the expiration date.

## 6. QUALITY CONTROL

**Internal Procedural Controls**

The COVID-19 Antigen Nasal Test Kit has built-in (procedural) controls. Each test device has an internal standard zone 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 Nasal 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, follow the advice from your local State or Territory Health Department for guidance on confirmation testing if necessary.
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 infectious. If you have symptoms or feel unwell seek medical assistance and ensure you follow the advice from your local State or Territory Health Department for guidance on confirmation testing if necessary.
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 rate of infection in the area, repeat testing within 1-3 day(s) 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 validation data available
13. A negative result does not rule out infection of other type of respiratory virus.

## 8. PERFORMANCE

**Detection Limit:** The detection limit for the COVID-19 Antigen Nasal Test Kit is less than 251 TCID50/mL..

**Clinical Evaluation:**

The performance of the COVID-19 Antigen Nasal Test Kit was established with 508 specimens collected and enrolled from individual symptomatic patients who were suspected of COVID-19. FDA EUA RT-PCR assay for the detection of SARS-CoV-2 was utilized as the comparator method for the study. The results were summarized below:

**Table: COVID-19 Antigen Nasal Test Kit vs. RT-PCR**

| | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| **COVID-19 Antigen Nasal Test Kit** | Positive | 104 | 1 | 105 |
| | Negative | 2 | 401 | 403 |
| Total | | 106 | 402 | 508 |

**Relative Sensitivity**: 98.1% (93.45% ~ 99.5%)* **Relative Specificity**: 99.8% (98.6% ~ 100.0%)*

**Overall Agreement**: 99.4% (98.3% ~ 99.8%)* *95% **Confidence Interval**

A Layperson study was evaluated with 106 laypersons from different age and different education to establish the performance and usability of COVID-19 Antigen Nasal Test Kit in a self-testing environment. The laypersons did the test while being observed by neutral trained personnel. The result shows the COVID-19 Antigen Nasal Test Kit and the underlying instructions for use are rated as a test that is easy to understand and perform and suitable for self-testing by laypersons. 100 subjects were enrolled and self-tested with package insert and quick reference guide only, relative sensitivity was 90.0% (27/30), relative specificity was 100.0% (60/60). The results showed that the labelling 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 Nasal 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, Pseudomonas Aeruginosa, Staphylococcus, Streptococcus. COVID-19 Antigen Nasal Test Kit might have cross-reactivity with human coronavirus HKU1 and SARS-CoV because they have high homology to the SARS-CoV-2

**Interfering Substances:**

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were evaluated. None of them were found to affect the performance of the COVID-19 Antigen Nasal Test Kit. 3 OTC nasal sprays, 3 OTC mouthwashes, 3 OTC throat drops, 4-acetamidophenol Adamantanamine, Acetylsalicylic acid, Albuterol, Chlorpheniramine, Dexamethasone, Dextromethorphan, Diphenhydramine, Doxylamine succinate, Flunisolide, Guaiacol glyceryl ether, Mucin, Mupirocin, Oxymetazoline Phenylephrine, Phenylpropanolamine, Oseltamivir phosphate, Tobramycin, Triamcinolone, Whole blood, Zanamivir

## 9. LITERATURE REFERENCES


1. Forni, D., Cagliani, R., Clerici, M. & Sironi, M. Molecular evolution of human coronavirus genomes. Trends Microbiol. 25, 35–48 (2017).
2 Ithete, N. L. et al. Close relative of human Middle East respiratory syndrome coronavirus in bat, South Africa. Emerg. Infect. Dis. 19, 1697–1699 (2013).


**Manufactured in Australia for:**

| | | | |
|---|---|---|---|
| REF | Catalog number | i | Temperature limitation |
| | Consult instructions for use | LOT | Batch code |
| IVD | In vitro diagnostic medical device | | Use by |
| | Manufacturer | | Contains sufficient for <n> tests |
| | Do not reuse | EC REP | Authorized representative in the European Community |
| CE | CE marking according to IVD Medical Devices Directive 98/79/EC | | |

IVD

CE

EC REP

Emergence Technology Pty Ltd.
Add: 6/3 Hill St, Toorak,
VIC, 3142, Australia

Assure Tech. (Hangzhou) Co., Ltd.
Building 4, No. 1418-50, Moganshan Road,
Gongshu District, Hangzhou,
310011 Zhejiang, P.R.China

Lotus NL B.V.
Koningin Julianaplein 10, le Verd,
2595AA,The Hague, Netherlands

**Manufacturer in New Zealand for:**

Supply Hub Direct
Unit 2C 25 Enfield St Mt Eden,
AKLD, 1024, New Zealand

## FREQUENTLY ASKED QUESTIONS (FAQ)

**1. How do I know if the Test worked well?**

The COVID-19 Antigen Nasal Test Kit is a rapid chromatographic immunoassay and detects SARS-CoV-2 viral antigens in nasal secretions through visual interpretation of colour development. Once the control line (C) appears, it means the test kit has performed properly.

**2. How soon can I read my results?**

The test results can be after 15 minutes as long as a coloured band or line appears in the Control region (C). Do not read result after 30 minutes.

**3. How to interpret the test if the colour and the intensity of the lines vary?**

The intensity of the colour in the Test area (T) varies. However, any shade in the Test area (T) should be considered positive.

**4. Can the result be incorrect and are there any factors that can affect the test result**?

The results will only give accurate results when carefully following the instructions. However, the result can be incorrect. Not pushing the collector into the extraction tube, insufficient sample size, expired tests are the most likely reasons for the missing.

**5. What do I have to do if the test result is positive?**

If you get a positive result, it indicates a possible SARS-CoV-2 infection. A positive result also means you are at risk of infecting others. Ensure you follow the advice from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance. Call your State and Territory hotline for further advice

**6. What do I have to do if the result is negative?**

Negative results do not completely rule out SARS-CoV-2 infection. Please continue to comply with all applicable rules regarding contact with others and protective measures. An infection can also be present if the test is negative. In case of suspicion, being in a high risk setting or where there is an occupational risk or other requirement, repeat the tests after 1-3 days and follow the advice from your local State or Territory Health Department for guidance on confirmation testing if necessary.

**7. Contact information for locally available support services.**

For advice on medical assistance or get confirmation tested for COVID-19 please contact your state or territory

| **CUSTOMER SUPPORT HELPLINE** | | |
|---|---|---|
| **Australia Freecall** | 1800 728 439 | 9am-7pm (AEST) |
| **New Zealand Freecall** | 0800 020015 | 9am-7pm (NZDT) |
| https://www.pathdx.com.au/salivapenhometest | | |
| **AUSTRALIA** | | |
| **Australian Capital Territory Department of Health** | | |
| 02 6207 7244 | https://health.act.gov.au/ | |
| **New South Wales Department of Health** | | |
| 137 788 | https://www.health.nsw.gov.au/ | |
| **Northern Territory Department of Health** | | |
| 1800 020 080 | https://health.nt.gov.au/ | |
| **Queensland Department of Health** | | |
| 134 268 | https://www.health.qld.gov.au/ | |
| **South Australian Department of Health** | | |
| 1800 253 787 | https://www.sahealth.sa.gov.au/ | |
| **Tasmanian Department of Health** | | |
| 1800 671 738 | https://www.health.tas.gov.au/ | |
| **Victorian Department of Health** | | |
| 1800 675 398 | https://www.health.vic.gov.au/ | |
| **Western Australian Department of Health** | | |
| 1800 595 206 | https://www.healthywa.wa.gov.au/ | |
| **TGA 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/ | | |
| **NEW ZEALAND** | | |
| For COVID-19 health advice and information, contact the Healthline (for free) on 0800 358 5453 or +64 9 358 5453 for international SIMS. For other COVID-19-related queries, email covid-19response@health.govt.nz | | |

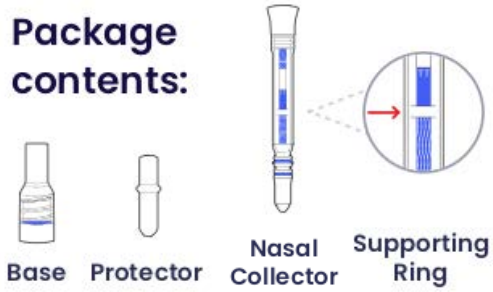
Version 2.2 – 07.01.2022

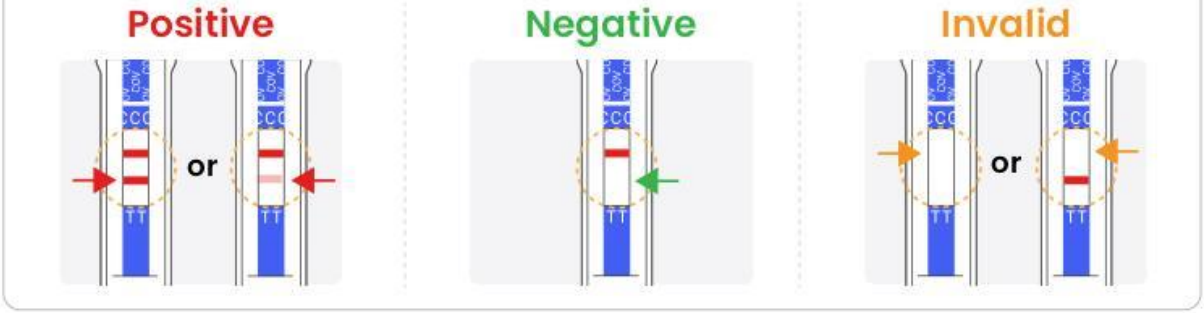
# COVID-19 Antigen Nasal Test Kit – Self Test Instruction Guide

To watch a demonstration video, visit **https://www.pathdx.com.au/nasalpenhometest.**

Australia Freecall 1800 728 439 9am-7pm (AEST)
New Zealand Freecall 0800 020015 9am-7pm (NZDT)

## Package contents:

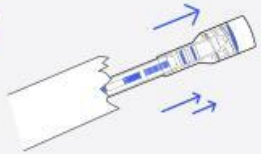



**Note: Use test only one time. Test within first 7 days of symptoms. Testing by adult or under adult supervision only.**

1. Wash your hands before the test.

2. Remove the test from the packaging.



3. Take the nasal collector out of the base.

4. Remove the protector from tip.

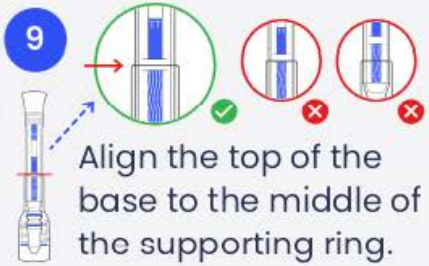
5. Rotate the collector five times against the nasal wall in left nostril

6. and then repeat in the right nostril.

7. If you have a nose stud in, use the other nostril and rotate 10 times.

8. Take collector from your nose and hold vertically

9. Align the top of the base to the middle of the supporting ring.



10. 30 mins / 15:00 minutes — Wait 15 minutes, then check your results. **Results will be invalid after 30 minutes.**

11. (Refer to **'Reading Results'** section above) - A **Positive** result shows **both** a control line **and** test line. **A faint test line should be considered positive.** Ensure you follow your own State or Territory's health authority guidelines. A **Negative** result shows **only** a control line and **no test line**. Monitor for symptoms. **No control line** means **Invalid** - re-test and make sure you push the collector firmly into the base. Call us for further advice.

12. Place the kit into a plastic bag and dispose of using your household waste or rubbish bin.