

COVID-19

Antigen Nasal Test Kit for Self-Testing

Quick Reference Instructions

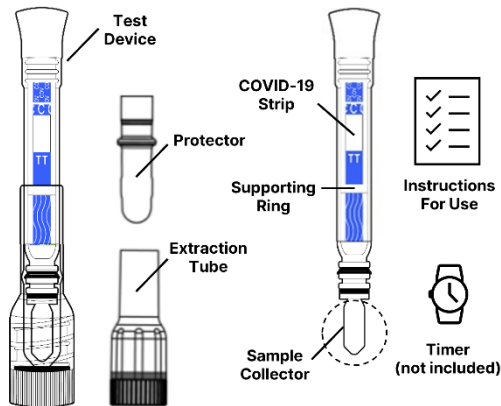


Scan QR Code for video or visit
www.biolink.net.au/biopen/v/nasal

Customer Support Helpline 1800 728 439
Customer Service Hours: 9AM-7PM AEST, 7 Days a week.

Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.

PACKAGE CONTENTS



STORAGE AND STABILITY

- Store at 2-30°C when not in use.
- DO NOT FREEZE.
- Do not use kit or components beyond the expiration date.

NOTE

!!! Children aged between 2 and 18 years old must be supervised or tested by an adult when carrying out the test.

!!! Do not use this test on anyone under 2 years of age.

!!! Caution when inserting the sample collector into the nasal cavity.

INTENDED USE

The COVID-19 Antigen Nasal Test Kit is an in vitro immunoassay that detects SARS-CoV-2 variants 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. The assay obtains a preliminary result only, aiding in the diagnosis of COVID-19. This test has not been cleared for use in asymptomatic individuals. Children aged between 2 and 18 years old must be supervised or tested by an adult when carrying out the test.

To download instructions for use, visit: www.biolink.net.au/biopen/v/nasal

BEFORE THE TEST

1. Bring devices, reagents, and specimens to room temperature (15-30°C) before use.
2. Remove the test device from its pack. For the best results, the assay should be performed within 1 hour.
3. Wash your hands with soap and water or use hand sanitizer for 20 seconds.

NASAL SWAB COLLECTION

1. Take the test device out of the extraction tube.
2. Remove the protector.
3. Gently insert the sample collector 1-2 cm into the nostril. Rotate the collector **five times** against the nasal wall and remove it from the nostril.
4. Repeat for the other nostril. Pull the swab out of the nose while twisting it slightly.



5. Repeat the sample collection procedure for the other nostril to ensure that sufficient specimen is collected from both nasal cavities.

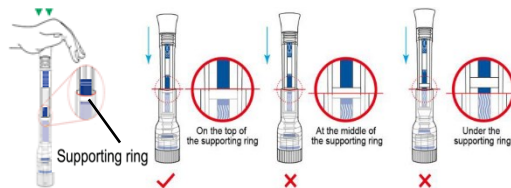
Note:

- Caution should be taken when inserting the sample collector into the nasal cavity.
- With children, the maximum depth of insertion into the nostril may be less than 2cm, and you may need to have a second person to hold the child's head while swabbing.
- This test may feel slightly uncomfortable or tickly, but it should not hurt. Do not insert the collector any deeper if you feel strong resistance.

WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected.

PROCESSING THE SAMPLE

1. Place the test device vertically into the extraction tube until the top edge of the extraction tube reaches the top of the supporting ring.

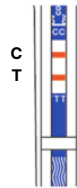


WARNING: When placing the test device vertically into the extraction tube, the edge of the extraction tube must reach the top of the supporting ring. If not, this may lead to lateral flow failure, resulting in an incorrect result or invalid result.

2. Read the results at **15 minutes**. Do not read the results after 30 minutes.

3. The used test kit should be placed into a waste bag and discarded as general waste. Please follow the local regulations for household waste disposal.

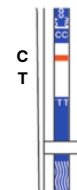
READING THE RESULTS



COVID-19 Positive: Two colored bands appear on the strip. One band appears in the control region (C) and another band appears in the test region (T).

A positive test result means it is very likely patients currently have COVID-19 disease. **Please follow the guidance from your local State or Territory Health Department for reporting of positive results and confirmation testing if necessary. If unwell, please consult a medical practitioner for follow up clinical care.**

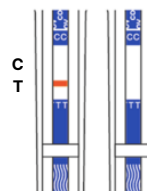
NOTE: There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens. **The shade of lines may vary. If a faint or weak line appears, it should be considered a positive result.**



COVID-19 Negative: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

A negative result for COVID-19 does not mean a person does not have COVID-19. If a person has symptoms, they should follow the guidance from the local state or territory health departments, and if unwell seek medical assistance.

NOTE: A negative result does not mean you are not infected with SARS-CoV-2. If you are unwell, please consult a medical practitioner for follow up care and continue to follow all public health advice on limiting the spread of COVID-19. If symptoms persist, test again within at least 24 hours and no more than 48 hours between tests as SARS-Cov-2 antigen present in COVID-19 cannot be precisely detected in all phases of an infection.



COVID-19 Invalid: No colored band appears in the control region (C), whether a test band(s) is present or not.

NOTE: Results from any test which has not produced a control band at the specified read time must be discarded. **Please review the procedure and repeat with a freshly collected sample and a new test. If the problem persists, please report repeated invalid results to the sponsor.**

PRINCIPLE

The COVID-19 Antigen Nasal Test Kit detects SARS-CoV-2 viral nucleoprotein antigens through visual interpretation of color development on the internal strip. AntiSARS-CoV-2 monoclonal antibodies (mAb) are immobilized on the test region of the nitrocellulose membrane. Additionally, anti-SARS-CoV-2 mAb 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. 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 antigen-antibody complex will be captured by the anti-SARS-CoV-2 mAb antibodies at the test region. Excess colored particles are captured at the control region of the nitrocellulose membrane.

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 a proper volume of specimen has been added and membrane wicking is working.

WARNINGS AND 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 between 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 anyone 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.
- Use only the supplied test components.
- Do not replace the buffer with any other liquid.
- Do not use the test kit if any of the components are missing.
- 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 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 extraction tube include salts, surfactants, sodium azide as preservative and water as solvent. Avoid skin or eye contact with the buffer. In the event of contact with buffer, rinse with plenty of water. Do not ingest.
- Keep the sample collector clean. Do not touch the collector and make sure it does not touch any surfaces before use. Place the sample collector in the extraction tube immediately after collecting the sample.
- COVID-19 Antigen Nasal Test Kit could detect SARS-CoV-2 variants alpha, beta, gamma, kappa, and delta.
- Test results should not be the sole basis for treatment or other management decisions.
- Do not puncture the foil membrane in the extraction tube before testing.
- Small test components can pose a choking hazard.
- Caution when inserting the sample collector into the nasal cavity.
- Do not use the test if you have a nosebleed. If your nose bleeds after swabbing, apply pressure to your nose and consult your health professional. Do not insert the swab again.
- If you have a nose piercing, sample the other nostril. If pierced on both sides, remove the piercing on one side before sampling.
- Dispose all parts of the used test kit into a waste bag, then discard the waste bag in the general waste.

LIMITATIONS

- 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."
- Children under 15 years old need adult supervision.
- Failure to follow the test procedure and interpretation of results may adversely affect and/or invalidate the test result.
- If the result is positive, follow the advice of your local state or territory health department for guidance on confirmation testing if necessary.
- 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.
- A positive result does not necessarily mean the patient is infected.
- 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.

