touch BIO

COVID-19 Rapid Antigen Test Kit (Nasal)

For Self-Testing — REF: VSCD02ST

A rapid antigen test for the detection of SARS-CoV-2 in a nasal swab.

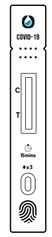
Read the instructions carefully before taking the test.

Australian Sponsor & Distributor: Touch Biotechnology Pty Ltd
Customer Support Number: 1300 166 282
Hours: 9am-7pm (AEST), or 9am-8pm (AEDT), 7 days per week
Website: www.touchaustralia.com.au
Email: touch@touchaustralia.com.au
Address: 119 Willoughby Road, Crows Nest, NSW 2065

Scan and Read the "How to Use" instructions
Scan the QR code for information on how to use the test.
SCAN ME

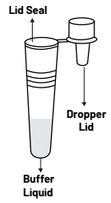
COMPONENTS PROVIDED

Test Cassette (Device)



Sterilized Swab

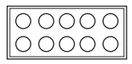
Extraction Buffer Tube



Instructions for Use

Biohazard Specimen Bag

Tube Stand



Only the 20-test kit contains a tube stand. Other test kits include a tube holder.

Component required but not provided:

TIMER

TEST PROCEDURE

STEP-1 Wash your hands

Wash or clean your hands and make sure they are dry before starting the test.

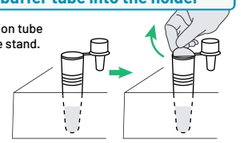
After washing your hands, open the box, and check the components before use.

STEP-2 Read Instructions for use

Read instructions for use carefully before using the test.

STEP-3 Place the buffer tube into the holder

- Carefully place extraction tube into tube holder or tube stand.
- Remove the seal.



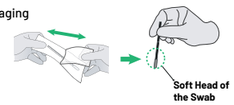
IMPORTANT

DO NOT DRINK the extraction buffer liquid.
If you accidentally drink it immediately consult a healthcare professional.

DO NOT SPILL any of the extraction buffer liquid. If you spill it, sterilize the area, and **repeat the test by using new sampling swab and extraction solution tube.**

STEP-4 Take the sterilized swab

Pull open the swab packaging at the marked point and remove the swab.



IMPORTANT

DO NOT TOUCH the soft head of the swab.
DO NOT OPEN the swab until you are going to use it immediately.

STEP-5 Sample Collection

- Tilt your head back slightly

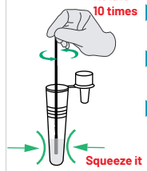
- Gently insert the swab about **2cm** into the **left nostril**. At least with the entire soft swab.
- Gently rotate the swab at least **5 times** against the nasal wall.
- Do the same for the **right nostril** Gently insert the swab about **2cm**. At least with the entire soft swab.
- Gently rotate the swab at least **5 times** against the nasal wall.
- Remove the swab from the second nostril.

IF YOU FEEL DISCOMFORT, STOP IMMEDIATELY.

IMPORTANT

If the swab stick breaks during the sample collection, please use a new swab.
Do not insert the swab deeper if you feel strong resistance or pain.

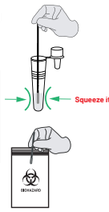
STEP-6 Insert the swab



- Insert the sampled swab into the extraction buffer tube, and dip the tip into the tube.
- Rotate the swab tip **10 times** along the inner wall of the buffer tube.
- And squeeze the tip of the swab **5 times** along the inner wall of the tube to keep as much liquid in the bottle as possible.

STEP-7 Take out the swab

- Remove the swab from the tube by squeezing the sides of the tube to release the liquid from the swab.

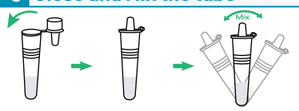


IMPORTANT

If squeezing of tube is not done correctly, the sample swab absorbs much more liquid form the extraction buffer and that will yield **wrong results**.

- Discard the swab in the **biohazard specimen bag.**

STEP-8 Close and Mix the tube



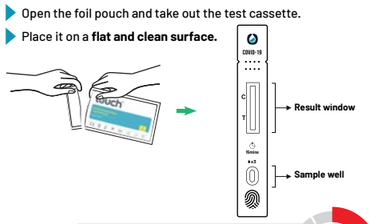
- Close the attached lid on the extraction tube.
- And then shake the extraction tube vigorously to **mix the specimen and the sample extraction buffer.**

IMPORTANT

Ensure **the lid is properly closed.**
Do not spill any of the sample extraction liquid.

STEP-9 Take out the cassette

- Open the foil pouch and take out the test cassette.
- Place it on a **flat and clean surface.**



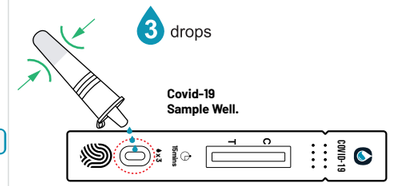
IMPORTANT

Perform the test within **15 minutes after the foil pouch is opened.**

15 min.

STEP-10 Test Operation

- Add **3 drops** of the extraction buffer tube to the **Covid-19 sample well marked "S"** on the test cassette.



IMPORTANT

Ensure that **at least 3 drops** of the liquid from the specimen tube are added to the sample well.
If adding less than 3 drops, that will yield wrong result.

STEP-11 Wait for result

- Set timer and wait for **15 minutes.**

Wait for 15 minutes

- Read the result at **15-20 minutes.**

Read at 15-20 Minutes

IMPORTANT

DO NOT READ the result beforehand or after 20 minutes, even If a line has already appeared at the region "C"

STEP-12 Read your results

To read your test results, please go to **the interpretation of the results** section provided below.

STEP-13 Disposal

Please dispose all parts of the test kits and place them in the **biohazard bag** that can be disposed in the **household waste or rubbish bin.**
If there are local regulations, please follow them.

STEP-14 Wash your hands

Wash your hands thoroughly after test completion.

Scan and Read the "How to Use" instructions
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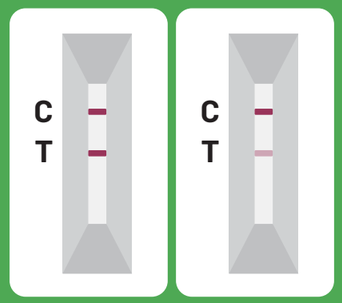
SCAN ME

INTERPRETATION OF THE RESULTS

Positive

SARS-CoV-2 Positive



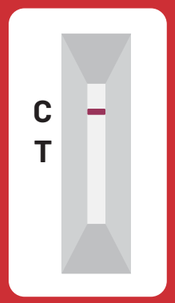
IF BOTH (C) AND (T) LINES ARE VISIBLE, SARS-COV-2 POSITIVE.

THE SHADE OF LINES MAY VARY, BUT EVEN IF A FAINT/ WEAK LINE APPEARS, IT SHOULD BE CONSIDERED POSITIVE.

If you test positive for COVID-19 or feel unwell and need advice, it's important to follow the guidance provided by the Department of Health and Aged Care. For more detailed information, please go to the next page and refer to "**What to do if you test positive?"** section.

Negative

SARS-CoV-2 Negative

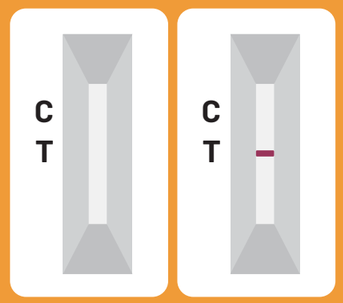


ONLY RED LINES APPEAR IN THE CONTROL REGION (C), AND NO LINE IN THE REGION (T).

The negative result indicates that there are no SARS-CoV-2 particles in the sample or the number of viral particles is below the detectable range. Even if you get a negative result, you still need to follow all public health advice on limiting the spread Covid-19.
If symptoms persist, repeat testing and consult a medical practitioner for follow-up clinical care.

Invalid

SARS-CoV-2 Invalid



NO RED LINE APPEARS IN THE CONTROL REGION (C) FOR SARS-COV-2.
The test is invalid even if there is a line on the region (T).

Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the control line (C) failure. Review the test procedure and repeat the test using a new test device. If invalid result continues after repeating, please contact **Touch Biotechnology** on the provided contact number or email for assistance.

NEED HELP with the TEST?

Before You Start

Do not open the foil pouch and swab packaging until you have read the instructions, and are ready to take the test. Use immediately upon opening.

Will this test hurt?

- No, the nasal swab is not sharp and it should not hurt. Sometimes the swab can feel slightly uncomfortable. If you feel pain, please stop the test and seek advice from a doctor.

When should I perform the test after opening the foil pouch?

- You should perform the test within 15 minutes after opening the foil pouch.

Don't know how long I should keep the swab out without using?

- Do not open the swab packaging until you are going to use it immediately.

What do you need to consider when storing the test kit?

- You can store the test kit at 2°C - 30°C temperature. Do not freeze and do not store the test kit in direct sunlight. All components must be bought to room temperature- before testing. Do not use after expiry date.

Sample Collection

Do I need to insert the swab into my both nostrils to take sample?

- Yes, you must take the samples from your both nostrils.

Don't know how deep I should insert the swab into my nostrils?

- Gently insert the swab about 2cm (soft head of the swab) into your nostrils. Do not insert the swab deeper if you feel strong resistance or pain.

Test Operation

How many drops should I add in both sample wells?

- You should add **3 drops** using the buffer tube into the sample wells noted as "S" on the cassette

Don't know how long I should wait to read my results?

- Make sure you wait for 15 minutes, and then read your results at 15-20 minutes.

Read Results

Not sure how to read the results?

- Region (C) is for Control, region (T) is for SARS-CoV-2. The line(s) next to these regions tell you your result. Turn over page and go to the interpretation of results section, and match your result. If you are not still sure how to read the results, scan QR Code to watch "how to use video".

How do I know if the test was run properly?

- A coloured line will appear in the control aregion (C) of the test cassette if the test has been properly performed. If this line is not visible, then the test has been incorrectly performed and you must run a new test or call customer support.

There is a faint/weak line appearing at T, should this be still considered as positive?

- Yes, even if there is a faint line at the region T or all, results must be considered as positive.

When is the test considered Invalid?

- When there is no line appearing on the control region (C), test must be considered invalid and you must repeat the test. Refer to Page-1 interpretation of test results section for more information.

What might lead to invalid test results?

- Insufficient sample volume or incorrect procedural techniques are the most likely reasons for the control line (C) failure. Review the test procedure again and repeat the test using the new test device. If invalid results continue after repeating, lease contact Touch Biotechnology Pty Ltd.

Visit www.touchaustralia.com.au/pages/ifu_covid to watch "how to use" video. If you have any specific questions, feedback or suggestion, please contact us on the provided contact number or email address.

SCAN ME

touch

COVID-19 Rapid Antigen Test Kit (Nasal)

For Self-Testing — REF: VSCD02ST

A rapid antigen test for the detection of SARS-CoV-2 in a nasal swab.
For Self-Testing use.
In-vitro diagnostic test for self-testing.

Instructions for use

INTENDED USE

The TouchBio COVID-19 Rapid Antigen Test Kit (Nasal) is an in vitro immunochromatographic assay for the qualitative detection of antigens in nasal swab specimens collected from patients against the respiratory infection for SARS-CoV-2 (within the first 7 days of the onset of symptoms). This test is intended for use as an aid in the differential diagnosis of SARS-CoV-2 viral infections in humans in conjunction with clinical and epidemiological risk factors.The test does not require any special training for sample collection, processing, or test operation. The TouchBio COVID-19 Rapid Antigen Test Kit (Nasal) is intended to be used by laypersons as a self-test. The test can be performed by individuals older than ≥ 18 years
old and users between 4-18 years old required guidance by adults. This kit is not suitable for children under 4 years old.

PRINCIPLE OF THE TEST

The TouchBio COVID-19 Rapid Antigen Test Kit (Nasal) is an immunochromatographic membrane assay and contains two independent tests, the SARS-CoV-2 antigen test. In the test procedure, a specimen is collected by nasal swab and placed onto sample well of test cassette as 3 drops for SARS-CoV-2 test zone. Then allow the solution in the sample well to migrate through the pads containing highly sensitive detector antibodies conjugated to gold dye for detection of nucleocapsid antigens.

MATERIALS AND COMPONENTS

Materials required and provided with the test kits:

COMPONENT	1 TEST KIT	2 TESTS KIT	5 TESTS KIT	20 TESTS KIT
Test Device	1 Test cassette (1 Test/pouch x 1 pouch)	2 Test cassettes (1 Test/pouch x 2 pouches)	5 Test cassettes (1 Test/pouch x 5 pouches)	20 Test cassettes (1 Test/pouch x 20 pouches)
Extraction Buffer Tube	1 single-use bottle, each with 500 µL extraction buffer	2 single-use bottles, each with 500 µL extraction buffers	5 single-use bottles, each with 500 µL extraction buffers	20 single-use bottles, each with 500 µL extraction buffers
Sterilised Swab	1 sterile, single use specimen sampling swab	2 sterile, single use specimen sampling swabs	5 sterile, single use specimen sampling swabs	20 sterile, single use specimen sampling swabs
Biohazard Specimen Bag	1 biohazard specimen bag	2 biohazard specimen bags	5 biohazard specimen bags	20 biohazard specimen bags
Instructions For Use	1 instructions for use	1 instructions for use	1 instructions for use	4 instructions for use
Tube Stand	-	-	-	1 Tube Stand

Materials required but not provided with the test kit:
Timer

STORAGE AND STABILITY

1. Store the test kit at 2°C - 30°C. DO NOT FREEZE and DO NOT STORE the test kit in direct sunlight. All components must be brought to room temperature before testing.
2. The test cassette must be used within 15 minutes after removal from the foil pouch.
3. DO NOT USE the test kit after the expiry date, which is stated on the label or packaging.

LIMITATIONS

1. Each test can only be used once
2. Test results must be read at 15 minutes and no later than 20 minutes.
3. A negative result does not rule out infection with another type of respiratory virus (other than SARS-CoV-2).
4. A negative result does not mean a person is not infectious or does not have COVID-19. If symptoms persist the person should seek medical attention and further testing if required.
5. Positive test results do not rule out bacterial infection or coinfection with other viruses.
6. A false negative test may result if the level of antigen in the sample is below the detection limit of the test or if the sample was collected incorrectly.
7. The test is less reliable in the later phase of infection and in asymptomatic individuals.
8. Children aged 4-18 years old should have the samples collected and tested by an adult. Do not use on Children under 4 years of age.
9. False negative results are more likely to occur if the test is performed after 7 days of symptom onset.
10. Even if the result is negative, you still need to observe all protective and hygienic measures,
11. Repeat Testing is recommended (between 24-48 hours after your first test if there is ongoing suspicion of infection, being high risk settling or where there is an occupational risk or otherrequirement.

QUALITY CONTROL

A colored line in the control area (C) is considered an internal process control. It confirms complete penetration of the membrane with the sample, reactivity of the reagents, and correct test performance.

PERFORMANCE CHARACTERISTICS

Clinical Study Performance

The clinical performance of the The TouchBio COVID-19 Rapid Antigen Test Kit (Nasal) was determined by comparison with an RT-PCR assay. Samples were taken within first 7 days of symptom onset and asymptomatic for SARS- CoV-2 The performance of theThe TouchBio COVID-19 Rapid Antigen Test Kit (Nasal) was assessed with 261 positive SARS-CoV-2 case by nasal swabs.

PERFORMANCE CHARACTERISTICS

SARS-CoV-2

TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test	PCR-RT comparative test result		
	Positive (+)	Negative(-)	Total
Positive	258	4	262
Negative	3	487	490
Total	261	491	752
Sensitivity: 258/261 x 100% = 98.85%			96.68% to 99.76%
Specificity: 487/491 x 100% = 99.19%			97.93% to 99.78%
Accuracy: (258+487)/752 x 100% = 99.07%			98.09% to 99.62%

Usability Study Performance

A total of 450 laysuers took part in the study for SARS-CoV-2 infections from which test correctly identified 98.47% as positive and 99.26% as negative.

Results for SARS-CoV-2:

SARS-CoV-2 Test Kit	RT-PCR comparison method		
	Positive	Negative	Total
Positive	310	1	311
Negative	5	134	139
Total	315	135	450
Sensitivity	310/315 x 100% = 98.41%		96.33% to 99.48%
Specificity	134/135 x 100% = 99.26%		95.94% to 99.98%
Accuracy	(310+134)/450 x 100% = 98.67%		97.12% to 99.51%

Analytical Performance

1.Limit of Detection (LOD)
The minimum detection limit of the The TouchBio COVID-19 Rapid Antigen Test Kit (Nasal) is 100 TCID50/mL for SARS-CoV-2 infections.

2.Variants
2.1.SARS-CoV-2
B.1.1.7 (Alpha), B.1.351 (Beta), P.1 (Gamma), B.1.617.2 (Delta), B.1.1.529 (Omicron).

3.Analytical Specificity
3.1.Cross Reactivity
The cross-reactivity of the kit was evaluated. The results showed no cross-reactivity with the following samplesthe following samples. Adenovirus Type 3, Adenovirus Type 5, Adenovirus Type 7, Human Parainfluenza Type 1,Human Parainfluenza Type 2, Human Parainfluenza Type 3, Human Parainfluenza Type 4, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus 229E, Respiratory syncytial virus Type A, Respiratory syncytial virus Type A, Respiratory syncytial virus Type B, Rhinovirus Type 1,Rhinovirus Type 14, Rhinovirus B70, Enterovirus CA16, Enterovirus 70, Avian influenza virus H7N9, Avian influenza virus H5N1, Human para-flu virus Type 1, Human para-flu virus Type 2, Human para-flu virus Type 3, Human para-flu virus Type 4, Cytomegalovirus, Measles virus, Boca virus, Mumps virus, Epstein Barr Virus, Herpes simplex virus (HSV-1), Varicella-zoster virus, Human metapneumovirus, MERS coronavirus, SARS-coronavirus, Human coronavirus (HKU1), Bordetella pertussis, Bordetella parapertussia, Staphylococcus epidermidis, Staphylococcusaureus, Staphylococcus pneumoniae, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus salivarus, Escherichia coli, Candida albicans, Mycobacterium tuberculosis, Paramyxovirus parotitis, Pneumocystis jirovecii, Moraxella catarrhalis, Pseudomonas aeruginosa, Pneumocystis, Legionella pneumophila, Corynebacterium pneumophila, Lactobacillispneumophila, Klebsiella pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumoniae, Neisseria pneumophila,Neisseria meningitides, Haemophilus influenza.
In silico analysis:
For Human Coronavirus HKU1, homology exists between the SARS-COV-2 nucleocapsid protein and Human Coronavirus HKU1. Blast results showed 36.6% homologous across 82% of the sequence. This is relatively low but cross-reactivity cannot be fully ruled out.

3.2.Interference Substances
The test results are not interfered by the substance in the following concentration. Whole Blood, Mucin, Benzocaine, Menthol, Zanamivir Mupirocin, Tobramycin, Fluticasone, Beclomethasone, Dexamethasone, Flunisolide, Triamcinolone, Mometasone, Sodium Chloride with preservative, Phenylephrine, Afrin (Oxymetazoline), Ibuprofen, Tetracycline, Chloramphenicol, Erythromycin, Arbidol, Ribavirin, Histamine dihydrochloride, Throat spray (Menthol), Mupirocine, Ice throat candy (Menthol), Tamiflu (Oseltamivir), Naphazoline hydrochloride nasal drops, Fisherman's Friend, Cromoglycate, Sinex (Phenylephrine Hydrochloride), Fluticasone propionate spray, Chloraseptic (Menthol/ Benzocaine), NasoGEL (NeilMed), CVS Nasal Spray (Cromolyn), Saline Nasal Spray, Zicam Cold Remedy, Homeopathic (Alkalol), Sodium Cromolyn Eye Drops, Alkalol Nasal Wash, Throat Lozenge, Sore throat phenol throat spray.

PRECAUTIONS

1.For self-testing in-vitro diagnostic use only.
2.Do not use the kit contents beyond the expiration date printed on the outside of the box.
3.Do not reuse the used Test Card, Reagent Tube or Swab.
4.The aluminum pouch includes a test cassette and a silica gel. Silica gel is required for protect test cassette against environmental conditions. Do not use the test kit if the aluminum pouch does not include silica gel. Do not swallow the silica gel. When swallowed, immediately consult your healthcare professional.
5.All users must read the instructions for use carefully before carrying out the test.

PRECAUTIONS

6.The sample buffer and test cassette must be brought to room temperature (18°C~30°C) before use, otherwise the results may be false.
7.Discard and do not use any damaged or dropped Test Card or material.
8.Users should test specimens as soon as possible after collection if the sample does not store in sample extraction solution.
9.Do not spill any of the sample extraction solution. If you spill it, sterilize the area and if the amount of the sample extraction solution mixture is not
enough to perform the test, repeat the test bey using new sampling swab and extraction solution tube.
10.Do not drink the extraction solution in the tube with or without swab. Immediately consult your healthcare professional if you drink it.
11.If the sample volume is insufficient, the assay will not perform successfully.
12.The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
13.Inadequate or inappropriate storage and transport of all components and sample collectionmay yield false test results.
14.To obtain accurate results, do not use visually bloody or overly viscous specimens.
15.To obtain accurate results, an opened and exposed Test Card should not be used in a heavily ventilated and moisture area.
16.Wash hands thoroughly after handling.
17.Do not touch the sample well or the membrane of the test cassette.
18.Keep out of reach of children.

Medical Device Incident Report
You can contact the Therapeutic Goods Administration (TGA) to report performance or usability issues via the online Users Medical Device Incident Report, emailing iris@tga.gov.au or calling 1800 809 361.

SYMBOLS USED

COMPONENT	Material included	BUFFER	Sample Buffer
	This Side Up	IVD	In Vitro Diagnostic Medical Device
	Fragile		Keep Away From Sunlight
IFU	Instruction for Use		Date of Manufacture
	Consult Instruction for Use	REF	Reference Number
Warning	Warning		Do Not Reuse
2°C 30°C 36°F 86°F	Store at 2°C ~ 30°C	LOT	Lot Number
	Expiration Date	n	Tests per Kit
	Manufacturer		Do not use if the package is damaged
	Keep Dry		

What to do if you test positive?

If you test positive for COVID-19 or feel unwell and need advice, it's important to follow the guidance provided by the Department of Health and Aged Care. For more detailed information, please visit their official website:
www.health.gov.au/topics/covid-19/testing-positive

Review the recommendations below from the Department of Health and Aged Care:

- If you have a Covid-19 POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.
- If you feel unwell or need COVID-19 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the healthdirect helpline on 1800 022 222.
- If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.

Australia Sponsor & Distributor
Touch Biotechnology Pty Ltd
Customer Support Number: 1300 166 282
Hours: 9am-7pm (AEST), or 9am-8pm (AEDT), 7 days per week
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