



TouchBio 5in1 - ADV, RSV, COVID-19 & Flu A/B Rapid Antigen Combo Test (Nasal)

For Self-Testing

REF: VMD798T

The test is to aid in the detection of SARS-CoV-2, Flu A, Flu B, RSV and ADV infection in 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: 4 Talavera Road Macquarie Park, NSW 2113

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



COMPONENTS PROVIDED

Only the 2D-test kit contains a tube stand. Other test kits include a tube holder.

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.

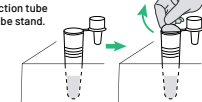
STEP-2 Read Instructions for use

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.

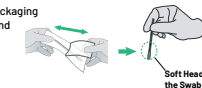


DO NOT DRINK the extraction buffer liquid. If you accidentally drink it immediately consult a healthcare professional.

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 sterilised swab

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



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.

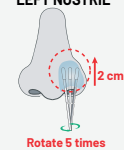
Gently rotate the swab at least 5 times against the nasal wall.

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.

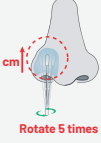
Remove the swab from the second nostril.

LEFT NOSTRIL



Rotate 5 times

RIGHT NOSTRIL



Rotate 5 times

IF YOU FEEL DISCOMFORT, STOP IMMEDIATELY.

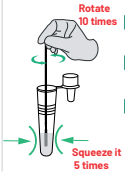
IMPORTANT If the swab stick breaks during the sample collection, please use a new swab. Do not insert the swab deeper if you feel strong resistance or pain.

STEP-6 Insert the swab

Rotate 10 times 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.



TEST PROCEDURE

STEP-7 Take out the swab

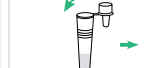
Remove the swab from the tube by squeezing the sides of the tube to release the liquid from the swab.



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.

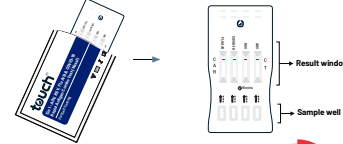


Ensure the lid is properly closed. Do not spill any of the sample extraction liquid.

STEP-9 Take out the cassette

Open the foil pouch and take out the test cassette.

Place it on a flat and clean surface.

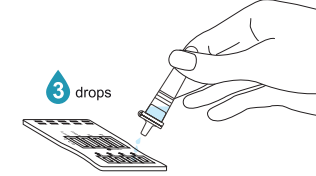


Perform the test within 15 minutes after the foil pouch is opened.



STEP-10 Test Operation

Add 3 drops of the extraction buffer tube into each sample well marked "S" on the test cassette.



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.



Read the result at 15-20 minutes.



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.



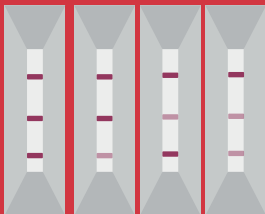
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INTERPRETATION OF THE RESULTS

Positive

FLU A/B Positive



If both C- and A-line are visible, Influenza A result
If both C- and B-line are visible, Influenza B result
If all three C- line, A line and B-line are visible, Influenza A and Influenza B test results are positive and valid.

FLU A Positive

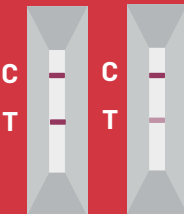


FLU B Positive



In rare cases, more than one virus may be present at the same time (co-infection). If the control line (C) and more than one test line (e.g. T and/or A and/or B) appear, this means you are positive for each virus indicated by a visible test line.

COVID-19, RSV, ADV Positive



If both C- and T-line are visible, result is considered positive for COVID-19 and/or RSV and/or ADV. Result should be considered as positive only for the virus against which lines appear. If you are infected to multiple viruses, then C-line and T-line will appear against each of that virus.

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

FLU A/B Negative



COVID-19, RSV, ADV Negative



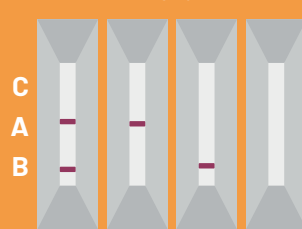
ONLY RED LINES APPEAR IN THE CONTROL REGION (C), AND NO LINE IN THE REGION (T).

You are considered negative only to those viruses against which T-line is missing however C-line appears. The negative result indicates that there are no any of these 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.

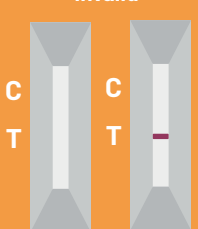
If symptoms persist, repeat testing and consult a medical practitioner for follow-up clinical care.

Invalid

FLU A/B Invalid



COVID-19, RSV, ADV Invalid



RESULTS ARE CONSIDERED INVALID: IF C-LINE IS NOT VISIBLE.

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.

INTENDED USE

TouchBio 5in1 - ADV, RSV, Covid-19 & FLU A/B Rapid Antigen Combo Test (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, adenovirus (ADV) and Respiratory syncytial virus (RSV) within the first 7 days of the onset of symptoms and influenza A/B within the first 4 days of the onset of symptoms. This test is intended for use as an aid in the differential diagnosis of SARS-CoV-2, influenza A/B, Respiratory syncytial virus (RSV), adenovirus (ADV) 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. Test kit is intended to be used by laypersons as a self-test. The test can be performed by individuals older than 2-18 years old and users between 2-18 years old required guidance by adults. This kit is not suitable for children under 2 years old.

SUMMARY

SARS-CoV-2: Novel coronaviruses belong to the β -genus. COVID-19 is an acute respiratory infectious disease. People are usually susceptible. Currently, patients infected by the novel coronavirus are the main source of infection; asymptomatic infected persons can also be an infectious source. According to current epidemiological surveys, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main symptoms are fever, fatigue and dry cough. In a few cases, nasal congestion, runny nose, sore throat, myalgia and diarrhea occur.

Influenza A/B: Influenza is a highly contagious acute viral infection of the respiratory tract. It is a contagious disease that is easily transmitted from person to person through aerosol droplets released when sneezing and coughing. Common symptoms include high fever, chills, headache, cough, sore throat and weakness. The type A influenza virus is more common and is the primary pathogen associated with severe outbreaks. The type B virus causes an illness that is usually not as severe as that caused by the type A virus.

RSV: Respiratory syncytial virus is a single-stranded (negative-stranded) RNA virus from the Paramyxoviridae family. It is the causative agent of a highly contagious, acute, viral infection of the respiratory tract. Almost half of all children are infected in the first year of life. It is also the main viral cause of hospital-acquired illness in children hospitalized for other reasons.

ADV: Adenoviruses most commonly cause respiratory illness, but depending on the infecting serotype, they can also cause a variety of other illnesses such as gastroenteritis, conjunctivitis, cystitis and rash disease. Symptoms of respiratory diseases caused by adenovirus infection range from the common cold syndrome to pneumonia, croup and bronchitis. Patients with weakened immune systems are particularly susceptible to serious complications of adenovirus infection. Adenovirus is transmitted through direct contact, fecal-oral transmission and sometimes through water. Some strains can establish persistent asymptomatic infections in the tonsils, adenoids and intestines of infected hosts, and shedding can occur for months or years.

MATERIALS AND COMPONENTS

Materials required and provided with the test kits

COMPONENT	1 TEST KIT	2 TESTS KIT	3 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)	3 Test cassettes (1 Test/pouch x 3 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 700 μ l extraction buffer	2 single - use bottles, each with 700 μ l extraction buffers	3 single - use bottles, each with 700 μ l extraction buffers	5 single - use bottles, each with 700 μ l extraction buffers	20 single - use bottles, each with 700 μ l extraction buffers
Sterilized Swab	1 sterile, single use specimen sampling swab	2 sterile, single use specimen sampling swabs	3 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	3 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	1 Instructions for use	4 Instructions for use
Tube Stand					1 Tube Stand

Materials required but not provided with the test kit: Timer

PRINCIPLE

TouchBio 5in1 - ADV, RSV, Covid-19 & FLU A/B Rapid Antigen Combo Test (Nasal) is an immunochromatographic membrane assay and includes four independent tests SARS-CoV-2, FLU A/B, RSV and ADV antigen tests.

The antigen test uses highly sensitive monoclonal antibodies to detect antigen in swab samples. These antibodies and a control protein are immobilized as two separate lines on a membrane support and combined with other reagents/pads to form a Test Strip. In antigen testing there is a test line and a control line. The test result is positive if either of the Test lines appears with the Control line in the test result window.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch at temperature 2-30°C. The kit is stable within the expiration date printed on the labeling.
- The test cassette must be used within 15 minutes after removal from the foil pouch.
- The kit must not be used after the expiry date. The expiry date is stated on the label/packaging.

CONTROL PROCEDURE

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.

LIMITATIONS

- Each test can only be used once.
- Test results must be read at 15 minutes and no later than 20 minutes.
- A negative result does not rule out infection with another type of respiratory virus (other than SARS-CoV-2, Influenza A/B, RSV and ADV).
- A negative result does not mean a person is not infectious or does not have COVID-19, Influenza A/B, RSV or ADV. If symptoms persist the person should seek medical attention and further testing if required.
- Positive test results do not rule out bacterial infection or coinfection with other viruses
- 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.
- If the result is positive for SARS-CoV-2, please contact the relevant state or territory health authority for guidance on confirmation testing.
- If positive for Influenza A/B, RSV and ADV are feeling unwell, consult a medical practitioner for follow-up clinical care.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.
- Children aged 2-18 years old should have the samples collected and tested by an adult. Do not use on Children under 2 years of age.
- False negative results are more likely to occur if the test is performed after 7 days of symptom onset for SARS-CoV-2, after 4 days of symptom onset for Influenza A/B and RSV, and after 6 days of symptom onset for ADV.
- Even if the result is negative, you still need to observe all protective and hygienic measures,
- Repeat Testing is recommended (between 24-48 hours after your first test if there is ongoing suspicion of infection, being high risk setting or where there is an occupational risk or other requirement.
- Influenza, RSV and ADV self-testing is for use as an aid for diagnosis only and individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.

PERFORMANCE CHARACTERISTICS

Analytical Performance

1. Limit of Detection (LOD)

For SARS-CoV-2, the minimum detection limit of the test kit is 100 TCID₅₀/mL
For Influenza A, the detection limit is minimum 1.0x10⁷ TCID₅₀/mL (A/Victoria/3/75) and maximum 5.0x10⁶ TCID₅₀/mL (A/HK/403946/09).

For Influenza B, the detection limit is minimum 6.0x10⁷ TCID₅₀/mL (B/17/04) and maximum 4.0x10⁶ TCID₅₀/mL (B-Yamagata).

For RSV, the detection limit is 240 TCID₅₀/mL.

For ADV, the detection limit is minimum being 3 TCID₅₀/mL (type 3) and maximum being 5.5x10⁷ TCID₅₀/mL (type 2).

2. Variants

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).
Influenza A variants: H1N1, H3N2, H1N1pdm09, A/Taiwan/42/06, A/HongKong/8/68, A/Victoria/3/75, A/14160, A/HK/403946/09, A/44045, A/924, A/Beijing/302/54, A/swine/Guangdong/2/01, S-OIV A/HK/415742/09, S-OIV A/California/4/09.

Influenza B variants: B-Victoria, B-Yamagata, B/17/15, B/17/04, B/179, B/668, B/Taiwan/2/62, B/Malaysia/2506/2004.

Respiratory syncytial virus (RSV) Variants: RSV A and RSV B.

Adenovirus (Adv) variants: Type 1, 2, 3, 4, 5, 7A, 40 and 41

3. Analytical specificity

Cross reactivity:

Cross reactivity of each analyte was assessed as below. The results showed no cross-reactivity with the following samples.

SARS-CoV-2, Influenza A, Influenza B and RSV

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 B, Rhinovirus Type 1, Rhinovirus Type 14, Rhinovirus B70, Enterovirus CA16, Enterovirus 70, 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 parapertussis, Staphylococcus epidermidis, Staphylococcus aureus, Staphylococcus pneumoniae, Streptococcus pyogenes, Streptococcus pneumoniae, Streptococcus salivarius, Escherichia coli, Candida albicans, Mycobacterium tuberculosis, Paramyxovirus parotitis, Pneumocystis jirovecii, Moraxella catarrhalis, Pseudomonas aeruginosa, Pneumocystis, Legionella pneumophila, Corynebacterium pneumophila, Lactobacillus pneumophila, Klebsiella pneumoniae, Mycoplasma pneumoniae, Chlamydia pneumoniae, Neisseria pneumophila, Neisseria meningitidis, Haemophilus influenzae.

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. Blast results showed no homology or sequence similarity between RSV sequence and HKU1, Mycobacterium tuberculosis & Pneumocystis jirovecii.

Adenovirus

Adenovirus Type 1, Adenovirus Type 2, Adenovirus Type 3, Adenovirus Type 4, Adenovirus Type 40, Adenovirus Type 41, Adenovirus Type 5, Adenovirus Type 7A, Cytomegalovirus, Enterovirus, Escherichia coli, Human Parainfluenza Virus, Influenza A Virus, Influenza B Virus, Legionella pneumophila, Measles Virus, Mumps Virus, Mycobacterium tuberculosis, Rhinovirus, RSV-A, SARS-Related Coronavirus 2, Streptococcus pneumoniae, Streptococcus pyogenes, Varicella Zoster Virus

PERFORMANCE CHARACTERISTICS-Continue

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), Mupirocin, Ice throat candy (Menthol), Tamiflu (Osetamivir), 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 (Alkaloi), Sodium Cromolyn Eye Drops, Alkaloi Nasal Wash, Throat Lozenge, Sore throat phenol throat spray.

Clinical Performance

SARS-CoV-2

TouchBio	PCR		Total
	Positive (+)	Negative(-)	
Positive	100	1	101
Negative	2	199	201
Total	102	200	302
Sensitivity:	99.04%		
Specificity:	99.50%		
Accuracy:	99.01%		

Influenza A

TouchBio	PCR		Total
	Positive (+)	Negative(-)	
Positive	102	2	104
Negative	1	198	199
Total	103	200	303
Sensitivity:	99.03%		
Specificity:	99.00%		
Accuracy:	99.01%		

ADV

TouchBio	PCR		Total
	Positive (+)	Negative(-)	
Positive	100	1	101
Negative	1	199	200
Total	101	200	301
Sensitivity:	99.01%		
Specificity:	99.50%		
Accuracy:	99.34%		

Usability Performance

SARS-CoV-2

TouchBio	PCR		Total
	Positive (+)	Negative(-)	
Positive	92	0	92
Negative	1	199	200
Total	93	199	243
Sensitivity:	98.92%		
Specificity:	100.00%		
Accuracy:	99.55%		

Influenza A

TouchBio	PCR		Total
	Positive (+)	Negative(-)	
Positive	94	1	95
Negative	2	149	151
Total	96	150	246
Sensitivity:	97.92%		
Specificity:	98.33%		
Accuracy:	98.78%		

ADV

TouchBio	PCR		Total
	Positive (+)	Negative(-)	
Positive	91	0	91
Negative	1	199	200
Total	92	199	242
Sensitivity:	98.91%		
Specificity:	100.00%		
Accuracy:	99.58%		

PRECAUTIONS

Please read all the information in this package insert before performing the test.

- For self-testing in-vitro diagnostic use only.
- Do not use the kit contents beyond the expiration date printed on the outside of the box.
- Do not reuse the used Test Card, Reagent Tube or Swab
- 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.
- All users must read the instructions for use carefully before carrying out the test.
- The sample buffer and test cassette must be brought to room temperature (18°C-30°C) before use, otherwise the results may be false.
- Discard and do not use any damaged or dropped Test Cassette or material.
- Users should test specimens as soon as possible after collection.

PRECAUTIONS-Continue

- Do not spill any of the sample extraction solution. If you spill it, sterilise the area and if the amount of the sample extraction solution mixture is not enough to perform the test, repeat the test by using new sampling swab and extraction solution tube.
- Do not drink the extraction solution in the tube with or without swab. Immediately consult your healthcare professional if you drink it.
- If the sample volume is insufficient, the assay will not perform successfully.
- The Reagent Solution contains a salt solution (saline). If the solution contacts the skin or eye, flush with copious amounts of water.
- Inadequate or inappropriate storage and transport of all components and sample collection may yield false test results.
- To obtain accurate results, do not use visually bloody or overly viscous specimens.
- To obtain accurate results, an opened and exposed Test Cassette should not be used in a heavily ventilated and moisture area.
- Wash hands thoroughly after handling.
- Do not touch the sample well or the membrane of the test cassette.
- Keep out of reach of children.
- Testing must be performed with extra caution and care for children under 5 years of age to avoid injuries in young children (e.g. do not apply pressure during swab collection or do not push the swab too deep into the nostril).

Medical Device Incident Report

You can contact the TGA to report performance or usability issues via the Users Medical Device Incident Report, email iris@tga.gov.au or call 1800 809 361

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

Individuals with a positive result for influenza, RSV, Adv or hMPV or who are unwell must consult a medical practitioner for follow-up clinical care.

For COVID-19, 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.

SYMBOLS USED			
COMPONENT	Material included	IFU	Instructions for Use
	Consult Instructions for Use		Expiration Date
	Store at 2°C - 30°C		Manufacturer
	Keep Dry		Do Not Reuse
	Lot Number		Reference Number
	Keep Away from Sunlight		Tests per Kit
	In-Vitro Diagnostic Medical Device		Do not use if the package is damaged

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

Website: www.touchbio.co.nz Email: touch@touchaustralia.com.au

Address: 4 Talavera Road Macquarie Park, NSW 2113

New Zealand Distributor: Touch Biotechnology Ltd

Customer Support Number: 0800 426 381

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