TouchBio RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test

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For Self-Testing | REF: K881416D | English

A rapid test for the qualitative detection of novel coronavirus antigens, influenza A&B virus, respiratory syncytical virus, adenovirus in nasal swab. For self-testing use.

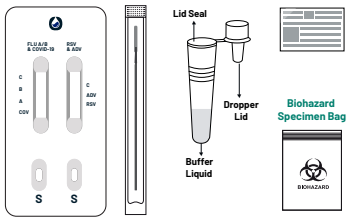
Read the instructions carefully before taking the test.

Australian 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



Component required but not provided: TIMER

STEP-1

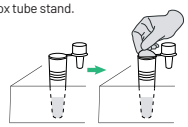
Wash or clean your hands and make sure they are dry before starting the test.

STEP-2

Read the instructions for use carefully.

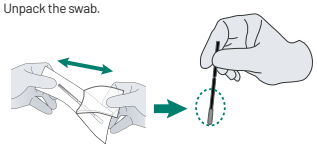
STEP-3

Take out one extraction tube, pull off the sealed aluminum foil on the extraction tube. Place extraction tube into tube stand or box tube stand.



STEP-4

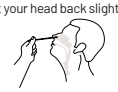
Unpack the swab.



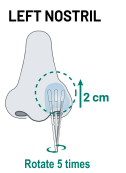
CAUTION: Do not touch swab tip when handling the swab.

STEP-5

Tilt your head back slightly.



Insert the swab about **2 cm** - at least with the entire soft swab tip - into the left nostril. Gently rotate the swab at least **five times** against the nasal wall.



STEP-6

Insert the same swab about **2 cm** - at least with the entire soft swab tip - into the **right nostril.**

Again, gently rotate the swab at least **five times** against the nasal wall.

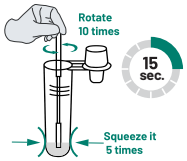
Remove the swab from the second nostril.

IMPORTANT If the swab stick breaks during the sample collection, please use a new swab.

STEP-7

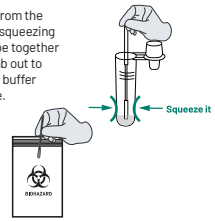
Dip the soft swab tip into the liquid.

Rotate the swab for at least **15 seconds** while pressing the head against the inside of the tube to dissolve the specimen in the liquid.



STEP-8

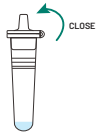
Remove the swab from the extraction tube by squeezing the sides of the tube together and pulling the swab out to ensure most of the buffer remains in the tube.



Discard the swab in the biohazard specimen bag.

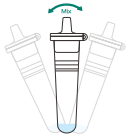
STEP-9

Screw on and tighten the nozzle onto the extraction tube.



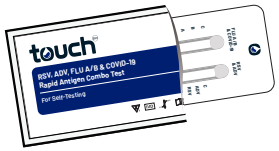
STEP-10

The tube should be gently shaken by inverting it or flicking the base for 30 seconds to mix the specimen to avoid the formation of foam or bubble and the sample extraction buffer.

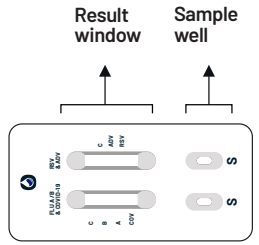


STEP-11

Open the foil pouch and take out the test cassette.



Place the test cassette on a flat and clean surface.

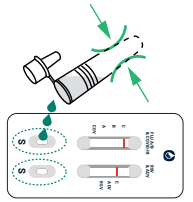


IMPORTANT Perform the test within **60 minutes** after the foil pouch is opened.

60 min.

STEP-12

Add 3 drops of the solution from the specimen collection tube to each sample well of the test cassette.



STEP-13

Set the timer for **15 minutes**.

IMPORTANT **Caution:** Do not read the result before hand, even if a line has already appeared at control region C. The test results will be **invalid if read after 20 minutes.**

STEP-14

Please dispose of the test materials in a biohazard specimen bag with the household refuse.If there are local regulations, please follow them.

STEP-15

Wash your hands thoroughly after test completion.

INTERPRETATION OF THE RESULTS

Positive

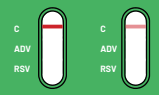
Weakly Positive

POSITIVE SARS-Cov-2: Two red lines appear. One red line appears in the control region (C), and one red line in the test region (Cov).
POSITIVE Influenza A: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza A region (A). A positive result in the Influenza A region indicates that Influenza A antigen was detected in the sample.
POSITIVE Influenza B: Two distinct colored lines appear. One colored line should be in the control region (C) and another colored line should be in the Influenza B region (B). A positive result in the Influenza B region indicates that Influenza B antigen was detected in the sample.
POSITIVE Influenza A and Influenza B: Three distinct colored lines appear. One colored line should be in the control region (C) and two colored line should be in the Influenza A region (A) and Influenza B region (B). A positive result in the Influenza A region and Influenza B region indicates that Influenza A antigen and Influenza B antigen were detected in the sample.
POSITIVE RSV: Two red lines appear. One red line appears in the control region (C), and one red line in the test region(Rsv). The shade of color may vary, but it should be considered positive whenever there is even a faint line.
POSITIVE ADV: Two distinct red lines appear. One red line should be in the control line region (C) and another apparent red line should be in the test line region(Adv)
*NOTE: The shade of color may vary, but it should be considered positive whenever there is even a faint line.

Negative

SARS-Cov-2 & FLU A/B

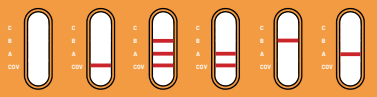
RSV & ADV



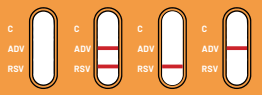
NEGATIVE: Only one red line appears in the control region (C), and no line in the test region(B/A/Cov/Adv/Rsv). If symptoms persist advice to conduct repeat testing and seek professional medical advice.

Invalid

SARS-Cov-2 & FLU A/B



RSV & ADV



INVALID: No red line appears in the control region (C). The test is invalid even if there is a line on test region(B/A/Cov/Adv/Rsv). Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the test procedure and repeat the test using a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

What to do if you test positive?

If you have a 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 advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222. If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.

INTENDED USE

TouchBio RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test (Nasal) is an *in-vitro* immunochromatographic assay for the qualitative detection of SARS-CoV-2 nucleoprotein antigen, influenza A/B nucleoprotein antigen, RSV F antigen and ADV hexon protein in nasal swab within 7 days of onset of symptoms as an aid for diagnosis of COVID-19, within 4 days of onset of symptoms as an aid for diagnosis of Influenza A/B, within 6 days of onset of symptoms as an aid for diagnosis of RSV and within 6 days of onset of symptoms as an aid for diagnosis of ADV using the rapid immunochromatographic method. This kit is intended for layperson's home use in a non-laboratory environment. (This product is not intended for children under three years old.)

PRINCIPLE OF THE TEST

TouchBio RSV, ADV, Flu A/B & COVID-19 Rapid Antigen Combo Test is a lateral flow immunoassay based on the principle of the double antibody sandwich technique. A monoclonal Covid-19/Flu A&B/RSV/Adv antibody conjugated with colored microparticles and sprayed onto the conjugation pad is used as a detector. During the test, the Covid-19/Flu A&B/RSV/Adv antigen in the sample interacts with the Covid-19/Flu A&B/RSV/Adv antibody conjugated with colored microparticles, creating an antigen-antibody labeled complex. This complex migrates on the membrane by capillary action up lo the Test line where ii is captured by the pre-coaled monoclonal Covid-19/Flu A&B/RSV/Adv antibodies. A colored test line (B/A/Cov/Adv/Rsv) would be visible in the each result window if Covid-19/Flu A&B/RSV/Adv antigens are present in the sample. The absence of the T line indicates a negative result. The control line (C) is for procedural control and should appear whenever the test procedure is being performed properly.

LIMITATIONS

- False positive results may occur, particularly in individuals without COVID-19 symptoms and/or individuals who live in areas with low numbers of Covid-19 infections and without known exposure to COVID-19.
- The test is an acute-phase screening test for qualitative detection. Sample collected may contain antigen concentration below the reagent's sensitivity threshold, so a negative test result does not exclude infection.
- The test detects viable and non-viable Influenza A and/or B virus and/or novel coronavirus antigen and/or RSV virus and/or ADV virus . Test performance depends on antigen load in the sample and may not correlate with cell culture performed on the same sample. A positive test does not rule out the possibility that other pathogens may be present, therefore, the results must be compared with all other available clinical and laboratory information to make an accurate diagnosis.
- Performance of the test has not been established for monitoring antiviral treatment of novel coronavirus.Positive test results do not rule out co-infections with other pathogens.
- The negative test results for novel coronavirus are not intended to rule in other coronavirus infection except the SARS-Cov-2.
- A negative result does not rule out infection with another type of respiratory virus.
- A negative result may occur if the concentration of antigen in a specimen is below the detection limit of the test or the specimen was collected or transported improperly, therefore a negative test result does not eliminate the possibility infection.
- Negative results may not mean that a person is not infectious and if symptoms persist, please seek medical advice.
- Recommend repeat testing within 1-3 days if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
- Risk of false-negative results for COVID-19, particularly if testing is not performed within the first 7 days of symptom onset.
- Risk of false-negative results for Influenza A/B, particularly if testing is not performed within the first 4 days of symptom onset.
- The tests are less reliable in the later phase of infection and in asymptomatic individuals.
- A positive result cannot necessarily determine whether a person is infectious.
- The Cross reactive study results show that the SARS-coronavirus affect the test results for Covid-19 and not affect the test results for Flu A/B and RSV and Adv.

MATERIALS AND COMPONENTS

Materials required and provided with the test kits:

COMPONENT	1 TEST/KIT	2 TESTS/KIT	5 TESTS/KIT
Test Device	1	2	5
Extraction Buffer Tube	1	2	5
Sterilised Swab	1	2	5
Biohazard Specimen Bag	1	2	5
Instructions For Use	1	1	1

Materials required but not provided with the test kit: Timer

STORAGE AND STABILITY

- Store the Rapid Test Cassette at room temperature or refrigerated (2-30°C). Do not freeze.
- All reagents are stable until the expiration dates marked on their outer packaging and buffer vial.
- Test sample within an hour after opening with RH<80%.

PERFORMANCE CHARACTERISTICS

Clinical Evaluaton

Using RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test by professional was compared to the RT-PCR kit. The sensitivity is 95.45% (105/110 known confirmed positive) for Covid-19 and 97.80% (88/90 known confirmed positive) for Flu A and 97.50% (39/40 known confirmed positive) for Flu B and 93.55% (58/62 known confirmed positive) for RSV and 98.33% (59/60 known confirmed positive) for Adv. The specificity is> 99.9% (480/480 known confirmed negatives) for Covid-19 and>99.9% (500/500 known confirmed negatives) for Flu A and> 99.9% (550/550 known confirmed negatives) for Flu B and> 99.9%(528/528 known confirmed negatives) for RSV And> 99.9% (530/530 known confirmed negatives) for Adv.

Usability Study

Using RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test by layperson was compared to the RT-PCR kit. The sensitivity is 97.22% (35/36) for Covid-19 , 96.77% (30/31) for Flu A, 96.97% (32/33) for Flu B, 96.77%(30/31)for RSV,> 99.99% (30/ 30) for Adv, the specificity is>99.99% (144/144) for Covid-19, >99.99% (116/116) for Flu A, >99.99% (116/116) for Flu B, >99.99% (149/149) for RSV and >99.99%(150/150) for Adv.

Variants Information

The following SARS-CoV-2 variants can be detected with RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test:P1 ,Delta and Omicron.
The following Influenza strains can be detected with RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test :A/Darwin/6/2021, A/Darwin/9/2021, A/Victoria/2570/2019, Hong Kong/2671/2019, A/Guangdong-Maonan/SWL 1536/2019, A/Brisbane/02/2018, A/Michigan/45/2015, A/Victoria/361/2011, A/Texas/50/2012,A/California/7/2009, A/SouthAustralia/34/2019, A/Switzerland/8060/2017, A/Singapore/INFIMH-16-0019/2016, A/Sydney/5/2021, B/Phuket/3073/2013(B/Yamagata lineage), B/Austria/1359417/2021 (B / Victorialineage) , B/Washington/02/2 0 19 (B/Victorialineage) , B/Colorado/06/2017 (B/Victoria/2/87 lineage), B/Massachusetts/2/2012.
The following RSV strains can be detected with RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test: A-2,Long,9320,Washington,B-1 wild type.
The following Adv strains can be detected with RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test: Adv Type 1,Type 2,Type 3,Type4,Type 5,Type 6,Type 7,Type 8, Type 11, Type 18, Type 23, and Type 55.

Limit of Detection (LOD)

The Limit of Detection (LoD) of the RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test is $6.25x10^2$ $TCID_{50}$/mL for Covid-19, $1.0xI0^2$ $TCID_{50}$/mL for Flu A(HINI), $1.0xI0^3$ $TCID_{50}$/mL for Flu B (B-Victoria Lineage), $2.4xI0^2$ $TCID_{50}$/mL for RSV (A-2), $1.8x10^2$ $TCID_{50}$/mL for Adv (Ad3).

Cross Reaction

The Cross reactive study results shows that the SARS-coronavirus affect the test results for SARS-CoV-2 . No cross-reactivity was observed with the othermicroorganisms and analytes tested. MERS-coronavirus, Legionella pneumophila (Bloomington-2, Los Angeles - 1, 82A3105) , Mycobacteriumtuberculosis (K, Erdman, HN878, CDC1551,H37Rv), Streptococcus pneumonia(4752-98 [Maryland (D1) 6B-17], 178 [Poland 23F-16], 262 [CIP 104340], Slovakia 14-10 [290551), Streptococcus pyrogens(Typing strain T1, [NCIB 11841, SF 130]), Mycoplasma pneumoniae(Mutant 22, FH strain of Eaton Agent [NCTC10119], 36M129-B7), Coronavirus(229E, OC43, NL63, HKU1), Human Metapneumovirus (hMPV) 3 Type B1 (Peru2-2002), Human Metapneumovirus (hMPV) 16 Type A1 (IA10-2003), Parainfluenza virus(Type 1, Type 2, Type 3, Type 4), Rhinovirus A16, candida albicans(CICC 1965), pseudomonas aeruginosa(ATCC9027), staphylococcus epidermis(ATCC 14990), staphylococcus salivarius(ATCC 25975), Enteroviruses(EV68, EV71), Chlamydia pneumoniae(VR2282), haemophilus influenzae (ATCC9006), bordetella pertussis(ATCC9340), Pneumocystis jirovecii(M167-6).
The kit can detect Covid-19, Flu AI B ,RSV and Adv in presence of co-infection.

Interfering Substances

When tested using the RSV, ADV, FLU A/B & COVID-19 Rapid Antigen Combo Test, there was no interference between the device reagents and the Potential interference substances listed in below that would create false positive or negative results:

Mucin; Whole Blood; Biotin; Neo-Synephrine (Phenylephrine); Afrin Nasal Spray (Oxymetazoline); Saline Nasal Spray; Homeopathic Zicam Allergy Relief Nasal Gel; Sodium Cromoglycate; Olopatadine Hydrochloride; Zanamivir; Oseltamivir; Artemetherlumefantrine; Doxycycline hyclate; Quinine; Lamivudine; Ribavirin; Daclatasvir; Acetaminophen; Staphylococcus aureus; Acetylsalicylic acid; Ibuprofen; Mupirocin; Tobramycin; Erythromycin; Ciprofloxacin; Ceftriaxone; Meropenem; Tobramycin; Histamine Hydrochloride;Peramivir; Flunisolide; Budesonide; Fluticasone; Lopinavir; Ritonavir; Abidor; Pooled human nasal wash; HAMA.

SAFETY AND INFORMATION

- Please dispose of the test materials in a closed plastic bag with the household refuse.
- Test kit buffer should only be used as directed; do not ingest.
- Do not dip the swab into provided solution or other liquid before inserting the swab into the nose.
- The buffer should avoid contact with skin and eyes.
- The buffer should keep out of the reach of children and pets at all limes before taking samples and after use.
- If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.

PRECAUTIONS

- For *in-vitro* diagnostic use only.
- Ensure foil pouch containing test device is not damaged before opening for use.
- Perform the test at room temperature 15 to 30°C.
- Do not substitute the swab and sample extraction buffer provided in this kit with components from other kits.
- Place the soft lip of the swab into the nostril.
- Strictly follow the operating instructions.
- The samples should be tested immediately after collection.
- Children aged 3 to 15 years old should have their samples collected and tested by an adult.
- Do not use the test for anyone under 3 years old.
- The test can only be used once.
- Please dispose of the used test materials in the medical waste bin.
- Test kit solutions should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and pets before and after use.
- If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water.

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@health.gov.au or calling 1800 809 361.

SYMBOLS USED

Symbol	Meaning	Symbol	Meaning
IVD	In vitro diagnostic medical device		Storage temperature limit
	Manufacturer	EC REP	Authorized representative in the European Community /European Union
	Date of Manufacture		Use-by date
	Do not re-use		Consult instructions for use or consult electronic instructions for use
LOT	Batch code		Do not use if package is damaged and consult instructions for use
REF	Catalogue number	Σ	Contains sufficient for <n> tests

Australian 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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Date of Issue: 20.03.2025
Version: V1.05