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touch

# TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test (Nasal)

REF: VMD71 EN

An Antigen Rapid Test for the detection of SARS-CoV-2, Flu A/B and RSV in nasal swab. **For Self-Testing use.**

IMPORTANT Read the instructions carefully before taking the test.

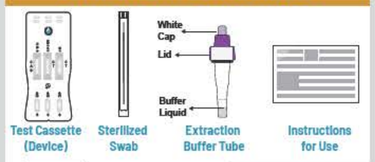

Australia Sponsor & Distributor
**Touch Biotechnology Pty Ltd**

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


**Watch "How to Use Video"**
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 20 tests/kit package contains the tube stand. The other test kits have a holder for the tube.

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.

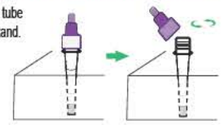
After washing your hands, open the box, and check the components before use.

### 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.
- Open the lid.

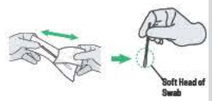


IMPORTANT **DO NOT DRINK** the extraction buffer liquid. If you accidentally drink it immediately consult your healthcare professionals.

**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.

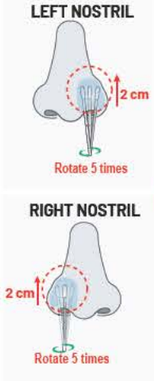



IMPORTANT **DO NOT TOUCH** soft head of swab.
**DO NOT OPEN** the swab until you are going to use it immediately.

### STEP-5 Sample Collection

- Tilt your head back slightly

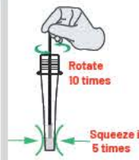

- Gently insert the swab about **2cm** into the **left nostril.** At least with the entire soft swab.
- Gently rotate the swab at least **5 times** against the nasal wall.
- Do the same for the **right nostril** Gently insert the swab about **2cm**. At least with the entire soft swab.
- Gently rotate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




IMPORTANT **IF YOU FEEL DISCOMFORT, STOP IMMEDIATELY.**

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.

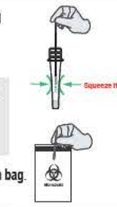
### STEP-6 Insert the swab




- 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, sample swab absorbs much more liquid form the extraction buffer and that will yield **wrong results.**

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

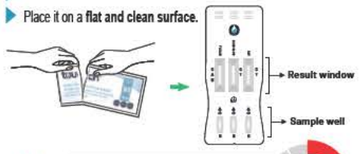
### STEP-8 Close and Mix the tube

- Screw on and tighten the 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 screwed on properly.**
**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.**

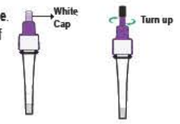



IMPORTANT Perform the test within **15 minutes after the foil pouch is opened.**

15 min.

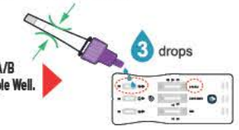
### STEP-10 Unscrew the white cap

**Unscrew the white cap of the tube.** This allows drop-wise dispensing of the liquid.

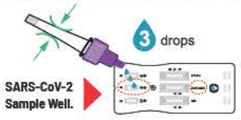



### STEP-11 Test Operation

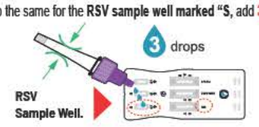
- Add **3 drops** of the extraction buffer tube to the **FLU A/B sample well marked "S"** on the test cassette.




- Do the same for the **SARS-CoV-2 sample well marked "S,** add **3 drops.**




- Do the same for the **RSV sample well marked "S,** add **3 drops.**




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

### STEP-12 Wait for result

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


- Read the result 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-13 Read your results

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

### STEP-14 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-15 Wash your hands

Wash your hands thoroughly after test completion.

**Watch "how to use" video:**
touchaustralia.com.au/pages/lfu-covid-flu-rsv

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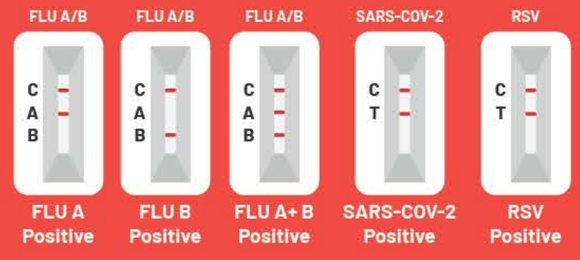
## INTERPRETATION OF THE RESULTS

**EACH TEST WINDOW (FLU A/B, SARS-CoV-2 AND RSV ) MUST BE READ INDEPENDENTLY FROM EACH OTHER.**

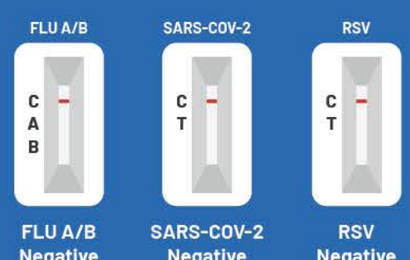
### POSITIVE RESULTS




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

If you have a POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance for SARS-CoV-2 and individuals with a positive result or who are unwell must consult a medical practitioner for follow-up clinical care for Influenza and RSV.

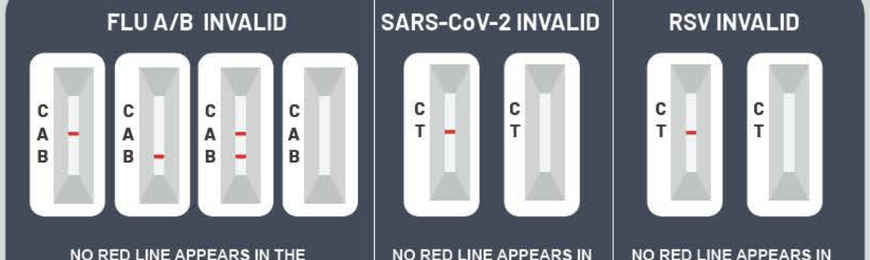
### NEGATIVE RESULTS




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

The negative result indicates that there are no Flu A/B, RSV and 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, Flu A/B and RSV. If symptoms persist, repeat testing and consult a medical practitioner for follow-up clinical care.

### INVALID RESULTS




NO RED LINE APPEARS IN THE CONTROL REGION (C) FOR FLU A/B.
The test is invalid even if there is a line on the region (A), (B) or (A) and (B).

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).

NO RED LINE APPEARS IN THE CONTROL REGION (C) FOR RSV.
The test is invalid evenif there is a line on the region (T).

**WHEN NO RED LINE APPEARS IN THE CONTROL REGION (C) FOR ALL THREE TESTS, THE TEST IS INVALID FOR ALL THREE FLU A/B, SARS-COV-2 AND RSV.**

**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.

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# 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 all three samples 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

**How do I know if the test was run properly?**

- A coloured line will appear in the control region (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 A, B or T, should this be still considered as positive?**

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

**The red line appeared in the control (C) region only on some of the strip/s and did not appear on one or two strips. Does that mean the test is invalid for all 3 viruses?**

- No, it means test must be considered invalid only for those virus where red line is absent on control (C) region. Results are valid for any test where control region (C) is present.

**Visit www.touchaustralia.com.au/pages/ifu-covid-flu-rsv 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

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# TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test (Nasal)

REF: VMD71 EN

An Antigen Rapid Test for the detection of SARS-Cov-2, Flu A/B and RSV in nasal swab. **For Self-Testing use.**

**In-vitro diagnostic test for self-testing**

# Instructions for use

## INTENDED USE

TouchBio RSV, FLU A/B & Covid-19 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 (within the first 7 days of the onset of symptoms) and influenza A/B or Respiratory syncytial virus (RSV) (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 and influenza A/B or Respiratory syncytial virus (RSV) 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. TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test (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

TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test (Nasal) is an immunochromatographic membrane assay and contains 3 independent tests, the SARS-CoV-2 antigen test, FLU A/B antigen test and RSV antigen test. In the test procedure, a specimen is collected by nasal swab and placed onto sample well of test cassette as 3 drops 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 K T | 2 TESTS K T | 5 TESTS K T | 20 TESTS K T |
|---|---|---|---|---|
| Test Device | 1 Tes casse e (1 Tes /pouch x 1 pouch) | 2 Tes casse es (1 Tes /pouch x 2 pouches) | 5 Tes casse es (1 Tes /pouch x 5 pouches) | 20 Tes casse es (1 Tes /pouch x 20 pouches) |
| Extraction Buffer Tube | 1 e ng e use bo e each w h 500 µ ex ac on bu e | 2 e ng e use bo es each w h 500 µ ex ac on bu e s | 5 e ng e use bo es each w h 500 µ ex ac on bu e s | 20 e ng e use bo es each w h 500 µ ex ac on bu e s |
| Sterilised Swab | 1 s e e ng e use spec men samp ng swab | 2 s e e ng e use spec men samp ng swabs | 5 s e e ng e use spec men samp ng swabs | 20 s e e ng e use spec men samp ng swabs |
| Biohazard Specimen Bag | 1 b ohaza d spec men bag | 2 b ohaza d spec men bags | 5 b ohaza d spec men bags | 20 b ohaza d spec men bags |
| Instructions For Use | 1 ns uc ons o use | 1 ns uc ons o use | 1 ns uc ons o use | 4 ns uc ons o use |
| Tube Stand | | | | 1 Tube S and |

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 after the expiry date. The expiry date is stated on the label/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, Influenza A/B and RSV).
4. A negative result does not mean a person is not infectious or does not have COVID-19, Influenza A/B or RSV. 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. If the result is positive for SARS-CoV-2, please contact the relevant state or territory health authority for guidance on confirmation testing.
8.If positive for Influenza A/B or RSV are feeling unwell, consult a medical practitioner for follow-up clinical care..
9. The test is less reliable in the later phase of infection and in asymptomatic individuals.
10. 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.
11. **False negative results are more likely to occur if the test is performed after 7 days of symptom onset for SARS-CoV-2 and after 4 days of symptom onset for Influenza A/B and RSV.**
12. Even if the result is negative, you still need to observe all protective and hygienic measures,
13. 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 other requirement.
14. Influenza and RSV 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.

## 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 kit was determined by comparison with an RT-PCR assay. Individual kits used in the clinical performances included combination antigen rapid test for COVID-19+FLU A/B and antigen rapid test for RSV. Samples were taken within first 4 days of symptoms onset for Influenza A+B, RSV and samples taken within 7 days of symptoms onset for SARS-CoV-2. The performance of the kit was assessed with 261 positive SARS-CoV-2 case, 223 positive cases of RSV 160 positive Influenza A case, and 120 positive influenza B case by nasal swabs.

**SARS-CoV-2**

| TouchBio RSV, FLU A/B & Covid-19 Rapid 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% |

**Influenza A+B**

| TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test | Influenza A RT-PCR Comparison Method | | | Influenza B RT-PCR Comparison Method | | |
|---|---|---|---|---|---|---|
| | Positive | Negative | Total | Positive | Negative | Total |
| Positive | 157 | 2 | 159 | 118 | 2 | 120 |
| Negative | 3 | 213 | 216 | 2 | 203 | 205 |
| Total | 160 | 215 | 375 | 120 | 205 | 325 |
| Sensitivity: | 98.12% | 94.62% to 99.61% | | 98.33% | 94.11% to 99.60% | |
| Specificity: | 99.07% | 96.68% to 99.89% | | 99.02% | 96.52% to 99.86% | |
| Accuracy: | 98.67% | 96.92% to 99.57% | | 98.77% | 96.86% to 99.66% | |

**RSV:**

| TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test | RT-PCR comparison method | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 220 | 1 | 221 |
| Negative | 3 | 230 | 233 |
| Total | 223 | 231 | 454 |
| Sensitivity | 98.65% | 95% CI | 96.12% to 99.72% |
| Specificity | 99.57% | 95% CI | 97.61% to 99.99% |
| Accuracy | 99.12% | 95% CI | 97.76% to 99.76% |

## Usability Study Performance

A total of 778 layusers took part in the TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test (Nasal) study. Results are summarized below.

**Results for SARS-CoV-2:**

The sensitivity is 98.28% and the specificity is 99.49%. The accuracy of the test kit is calculated as 99.04%.

| RSV, FLU A/B & Covid-19 Rapid Antigen Combo Tes | RT-PCR comparison method | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 114 | 1 | 115 |
| Negative | 2 | 194 | 196 |
| Total | 116 | 195 | 311 |

**Results for Influenza A:**

The sensitivity is 98.39% and the specificity is 100.0%. The accuracy of the test kit is calculated as 99.21%.

| RSV, FLU A/B & Covid-19 Rapid Antigen Combo Tes | RT-PCR comparison method | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 183 | 0 | 183 |
| Negative | 3 | 195 | 198 |
| Total | 186 | 195 | 381 |

**Results for Influenza B:**

The sensitivity is 98.86% and the specificity is 100.0%. The accuracy of the test kit is calculated as 99.46%.

| RSV, FLU A/B & Covid-19 Rapid Antigen Combo Tes | RT-PCR comparison method | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 174 | 0 | 174 |
| Negative | 2 | 195 | 197 |
| Total | 176 | 195 | 371 |

**Results for RSV:**

The sensitivity is 97.14% and the specificity is 99.49%. The accuracy of the test kit is calculated as 98.67%..

| RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test | RT-PCR comparison method | | |
|---|---|---|---|
| | Positive | Negative | Total |
| Positive | 102 | 1 | 103 |
| Negative | 3 | 194 | 197 |
| Total | 105 | 195 | 300 |

## Analytical Performance

### 1.Limit of Detection (LOD)

The minimum detection limit of the TouchBio RSV, FLU A/B & Covid-19 Rapid Antigen Combo Test (Nasal) is 100 $TCID_{50}$/mL for SARS-CoV-2 infections. For Influenza A, the detection limit is minimum $1.0x10^2$ $TCID_{50}$ /mL (A/Victoria/3/75) and maximum $5.0x10^4$ $TCID_{50}$/mL (A/HK/403946/09) and for Influenza B, the detection limit is minimum $6.0x10^2$ $TCID_{50}$/mL(B/1704) and maximum $4.0x10^4$ $TCID_{50}$/mL (B-Yamagata). For RSV, the detection limits is 240 $TCID_{50}$/mL.

### 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).

#### 2.2 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.

#### 2.3.Influenza B variants

B-Victoria, B-Yamagata, B/1715, B/1704, B/179, B/668, B/Taiwan/2/62, B/ Malaysia/2506/2004.

#### 2.4.Respiratory syncytial virus (RSV) Variants

RSV A and RSV B.

### 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 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, Staphylococcus aureus, 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, Lactobacillus pneumophila, 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.
Blast results showed no homology or sequence similarity between RSV sequenece and HKU1, Mycobacterium tuberculosis & Pneumocystis jirovecii.

#### 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.
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

**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 |
| | Store at 2°C ~ 30°C | LOT | Lot Number |
| | Expiration Date | | Tests per Kit |
| | Manufacturer | | Do not use if the package is damaged |
| | Keep Dry | | |

## STATE AND TERRITORY CONTACT NUMBERS

**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.

**Local state and territory health departments**
Contact details and websites of the local state and territory health departments

**•Australian Capital Territory Coronavirus Helpline**
Coronavirus helpline (8am to 8pm daily): 02 6207 7244
Business hours: 02 5124 9213 Website: https://health.act.gov.au/

**•New South Wales Department of Health**
General enquiries: 1300 066 055
Coronavirus hotline (Service NSW, 24/7): 137 788
Website: https://www.health.nsw.gov.au/

**•Northern Territory Department of Health** General enquiries: 08 8922 8044
Coronavirus hotline (National helpline): 1800 020 080 Website: https://health.nt.gov.au/

**•Queensland Department of Health**
General enquiries: 13HEALTH or 13 432 584 Coronavirus hotline: 134COVID or 134 268 Website: https://www.health.qld.gov.au/

**•South Australian Department of Health**
General enquiries: 1300 232 272
Coronavirus hotline (9am to 5pm daily): 1800 253 787
Website: https://www.sahealth.sa.gov.au/

**•Tasmanian Department of Health**
General enquiries:1300 135 513
Public Health Hotline (coronavirus): 1800 671 738
Website: https://www.health.tas.gov.au/

**•Victorian Department of Health**
Department of Health and Human Services: 1300 650 172
Victorian coronavirus hotline (24/7): 1800 675 398
Website: https://www.dhhs.vic.gov.au/

**•Western Australian Department of Health**
General enquiries: 08 9222 4222
Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri) or 1800 595 206 Website: https://www.healthywa.wa.gov.au/

**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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