

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

IMPORTANT Read the instructions carefully before taking the test.

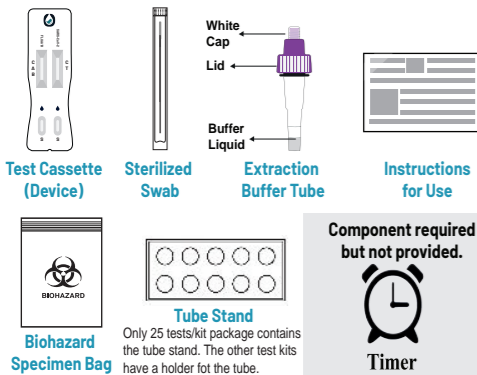
Australia Sponsor & Distributor
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Watch "How to Use Video"
 Scan the QR code for information on how to use the test.



COMPONENTS PROVIDED



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. Rotate 5 times

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. 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

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

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. Ensure to add at least 3 drops of the liquid from the specimen tube in to 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. 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-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: www.touchaustralia.com.au/pages/ifu

INTERPRETATION OF THE RESULTS

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

+ POSITIVE RESULTS

FLU A Positive **FLU B Positive** **FLU A/B Positive** **SARS-CoV-2 Positive** **FLU A/B and SARS-CoV-2 Positive**

IF BOTH (C) AND (A) LINES ARE VISIBLE, INFLUENZA A POSITIVE.
 IF BOTH (C) AND (B) LINES ARE VISIBLE, INFLUENZA B POSITIVE.
 IF ALL THREE (C), (A), AND (B) LINES ARE VISIBLE, INFLUENZA A AND INFLUENZA B POSITIVE.
 IF BOTH (C) AND (T) LINES ARE VISIBLE, SARS-COV-2 POSITIVE.
 IF ALL LINES ARE VISIBLE, INFLUENZA A, INFLUENZA B AND 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 have a POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance if necessary. If you are 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.

- NEGATIVE RESULTS

FLU A/B and SARS-CoV-2 Negative

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 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 and Flu A/B. **If symptoms persist, repeat testing and consult a medical practitioner for follow-up clinical care.**

? INVALID RESULTS

FLU A/B INVALID **SARS-CoV-2 INVALID**

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).

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

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 both 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?

- On the Test Cassette(Device), there are Flu A/B and SARS-CoV-2 windows, each window has its own region. Region (C) is for Control, region (A) is for Influenza A, region (B) is for Influenza B, 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 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..

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, please contact Touch Biotechnology Pty Ltd.

The red line did NOT appear in the control (C) for FLU A/B test, but it appeared in the control (C) for the SAR-CoV-2 test. Does that mean the test invalid for either of them?

- No, it means the test is considered invalid ONLY for FLU A/B, results are still considered valid for SARS-CoV-2.

The red line did NOT appear in the control (C) for SAR-CoV-2 test but it appeared in the control (C) for the FLU A/B test. Does that mean the test invalid for either of them?

- No, it means the test is considered invalid ONLY for SAR-CoV-2 test, results are still considered valid for FLU A/B.



Visit www.touchostralia.com.au/pages/ifu 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.



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TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (Nasal)

REF: VSCD10ST

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

In-vitro diagnostic test for self-testing

Instructions for use

INTENDED USE

The TouchBio SARS-CoV-2 & FLU A/B 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 (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 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 SARS-CoV-2 & FLU A/B 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

The TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (Nasal) is an immunochromatographic membrane assay and contains two independent tests, the SARS-CoV-2 antigen test, and the FLU A/B 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 FLU A/B test zone and 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	25 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)	25 Test cassettes (1 Test/pouch x 25 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	25 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	25 sterile, single use specimen sampling swabs
Biohazard Specimen Bag	1 biohazard specimen bags	2 biohazard specimen bags	5 biohazard specimen bags	25 biohazard specimen bags
Instructions For Use	1 instructions for use	1 instructions for use	1 instructions for use	25 instructions for use
Tube Stand	-	-	-	1 Tube Stand

Materials required but not provided with the test kit
-Timer

STORAGE AND STABILITY

- 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.
- The test cassette must be used within 15 minutes after removal from the foil pouch.
- DO NOT USE after the expiry date. The expiry date is stated on the label/packaging.

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 and Influenza).
- A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention and further testing if required.

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.health.wa.gov.au/>

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- 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 or 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 4-18 years old should have the samples collected and tested by an adult. Do not use on Children under 4 years of age.
- False negative results are more likely to occur if the test is performed after 7 days of symptom onset.**

- 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 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 TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (Nasal) was determined by comparison with an RT-PCR assay. Samples were taken within first 4 days of symptom onset for Influenza A+B, and samples taken within first 7 days of symptom onset and asymptomatic for SARS-CoV-2. The performance of the TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (Nasal) was assessed with 261 positive SARS-CoV-2 case, 160 positive Influenza A case, and 120 positive influenza B case by nasal swabs.

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%

Influenza A+B

SARS-CoV-2 & FLU A/B Combo Test Kit	Influenza A			Influenza B		
	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 99.80%			
Specificity: 99.07%	96.68% to 99.89%	99.02%	96.52% to 99.88%			
Accuracy: 98.67%	96.92% to 99.57%	98.77%	96.88% to 99.66%			

Usability Study Performance

A total of 1100 layusers took part in the TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (Nasal) study, which included 450 SARS-CoV-2 infections from which test correctly identified 98.47% as positive and 99.26% as negative. Study included 350 Influenza A infections from which test correctly identified 98.78% as positive and 99.05% as negative. Also included 300 Influenza B infections from which test correct identified 99.05% as positive and 100% as negative.

Results for SARS-CoV-2:

SARS-CoV-2 & Flu A/B Combo 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%

Results for Influenza A:

SARS-CoV-2 & Flu A/B Combo Test Kit	RT-PCR comparison method		
	Positive	Negative	Total
Positive	242	1	243
Negative	3	104	107
Total	245	105	350
Sensitivity	242/245 x 100% = 98.78%		96.46% to 99.75%
Specificity	104/105 x 100% = 99.05%		94.81% to 99.98%
Accuracy	(242+104)/350 x 100% = 98.57%		97.10% to 99.69%

Results for Influenza B:

SARS-CoV-2 & Flu A/B Combo Test Kit	RT-PCR comparison method		
	Positive	Negative	Total
Positive	208	0	208
Negative	2	90	92
Total	210	90	300
Sensitivity	208/210 x 100% = 99.05%		96.46% to 99.75%
Specificity	90/90 x 100% = 100%		95.98% to 100%
Accuracy	(208+90)/300 x 100% = 99.33%		97.61% to 99.92%

Analytical Performance

1.Limit of Detection (LOD)

The minimum detection limit of the TouchBio SARS-CoV-2 & FLU A/B Antigen Combo Test (Nasal) is 100 TCID50/mL for SARS-CoV-2 infections. For Influenza A, the detection limit is minimum 1.0x10² TCID50/mL (A/Victoria/3/75) and maximum 5.0x10⁴ TCID50/mL (A/HK/403946/09) and for Influenza B, the detection limit is minimum 6.0x10² TCID50/mL(B/1704) and maximum 4.0x10⁴ TCID50/mL (B-Yamagata).

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.

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 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 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 (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 (Alkalol), Sodium Cromolyn Eye Drops, Alkalol Nasal Wash, Throat Lozenge, Sore throat phenol throat spray.

PRECAUTIONS

- 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 Card or material.
- Users should test specimens as soon as possible after collection if the sample does not store in sample extraction solution.
- 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 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 Card 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

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
[i]	Consult Instruction for Use	[REF]	Reference Number
⚠️	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