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REF:K861416D

English

RSV, INFLUENZA A/B & COVID-19 RAPID ANTIGEN COMBO TEST (NASAL)

An Antigen rapid test for the detection of SARS-Cov-2 and influenza A/B and RSV virus in nasal swab. For self-testing use.

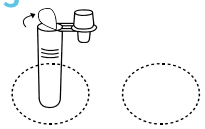
1

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

2

Read the instruction for use carefully.

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.

4

Unpack the swab. **Caution:** Do not touch swab tip when handling the swab.

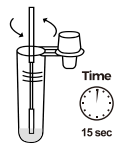
5

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.

6

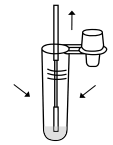
Insert the same swab about 2 cm - at least with the entire soft swab tip - into the right nostril. Again, gently rotate the swab at least five times against the nasal wall. Remove the swab from the second nostril. Caution: If the swab stick breaks during specimen collection, please use a new swab.

7



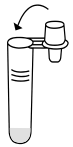
Dip the soft swab tip into the liquid. Rotate the swab for at least 15 seconds while pressing the head against the inside of the tube to dissolve the specimen in the liquid.

8



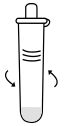
Remove the swab from the extraction tube by squeezing the sides of the tube together and pulling the swab out to ensure most of the buffer remains in the tube. Discard swab in biohazard specimen bag.

9



Screw on and tighten the nozzle onto the extraction tube.

10

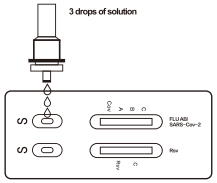


The tube should be gently shaken by inverting it or by flicking the base for 30 seconds to mix the specimen to avoid the formation of foam or bubbles and the sample extration buffer.

11

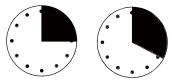
Open the foil pouch and take out the test cassette. Place the test cassette on a flat, clean surface. CAUTION: Perform the test within 60 minutes after the foil pouch is opened.

12



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

13



Set timer for 15 minutes. 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.

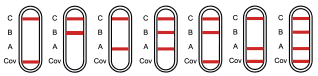
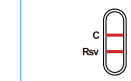
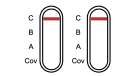
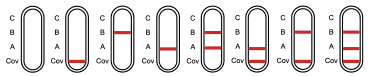
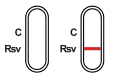
14

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

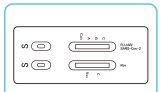
15

Wash hands thoroughly after test completion.

INTERPRETATION OF RESULTS

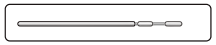
POSITIVE		NEGATIVE		INVALID	
Covid-19 & Influenza A&B	**RSV**	**Covid-19 & Influenza A&B**	**RSV**	**Covid-19 & Influenza A&B**	**RSV**
					
POSITIVE Covid-19: Two red lines appear. One red line appears in the control region (C) , and one red line in the test region (Cov). **POSITIVE Influenza A:** Two red 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 red lines appear. One colored line should be in the control region (C) and another colored line should be in Influenza B region(B). A positive result in Influenza B region indicates that Influenza B antigen was detected in the sample.	**POSITIVE RSV:** Two red lines appear. One red line appears in the control region(C), and one redline in the test region(Rsv). The shade of color may vary, but it should be considered positive whenever there is even a faint line.	**NEGATIVE:** Only one red line appears in the control region(C), and no line in the test region(Cov/A/B/Rsv).		**INVALID:** No red line appears in the control region(C). The test is invalid even if there is a line on test region(Cov/A/B/Rsv). Insufficient sample volume or incorrect procedural techniques are the mostlikely reasons for control line failure.	
Caution: The shade may vary, but if even a faint line appears, it should be considered positive. If you have a Covid-19 POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary and the need to seek guidance from your local State or Territory Health Department for reporting of positive results if required, if unwell seek medical assistance. If you have a Influenza or RSV POSITIVE result, individuals are advised to consult a medical practitioner for follow-up clinical care.		**Caution:** If you have symptoms like fever, cough and/or shortness of breath. Please retest in 1-3 days. You must continue following the applicable hygiene and distancing rules even with a negative result. If symptoms persist or if unwell please consult a medical practitioner for follow-up clinical care".		**Caution:** Review the test procedure and repeat the test with a new test cassette and a freshly collected sample. If the problem persists, discontinue using the test kit immediately and contact your sponsor.	

MATERIALS PROVIDED

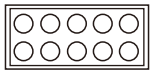

Test device


Package Insert


Extraction Tube with buffer


Sterilized Swab
(The information about the swab can be found on its packaging.)


Biohazard Specimen Bag


Tube stand
(The 25 tests/kit package contains the tube stand,the 1 test/kit , 2 tests/kit and 5 tests/kit package use the test box itself as tube stand.)
Materials required but not provided : Timer

QR CODE INSERT

Scan the QR code for information on how to use the RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal).

• Australia Sponsor: Sonictec Pty Ltd
• Customer Support Number: 02 8328 1008
• Address: 17 Chisholm St, Wolli Creek NSW 2205
• Hours: 10am-5pm, Monday - Friday
• Email: info@sonictec.com.au
• Website:www.sonictec.com.au/4in1

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REF:K861416D
English

RSV, INFLUENZA A/B & COVID-19 RAPID ANTIGEN COMBO TEST (NASAL)

INTENDED USE

This kit is intended for the qualitative detection of SARS-CoV-2 nucleoprotein antigen , influenza A/B nucleoprotein antigen and RSV F antigen using the rapid immunochromatographic method in human anterior nasal swab specimens from individuals 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 and RSV.
This kit is intended for layperson' s home use in a non-laboratory environment (e.g. in a person's residence or certain non-traditional places such as offices, sporting events, airports, schools, etc.).

PRINCIPLE

The RSV, Influenza 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 SARS-CoV-2/Influenza A&B/RSV antibody conjugated with colored microparticles and sprayed onto the conjugation pad is used as a detector. During the test, the SARS-CoV-2/Influenza A&B/RSV antigen in the sample interacts with the SARS-CoV-2/Influenza A&B/RSV antibody conjugated with colored microparticles, creating an antigen-antibody labeled complex. This complex migrates on the membrane by capillary action up to the Test line where it is captured by the pre-coated monoclonal SARS-CoV-2/Influenza A&B/RSV antibodies. A colored test line (T) would be visible in the each result window if SARS-CoV-2/Influenza A&B/RSV 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.

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℃.
- Do not substitute the swab and sample extraction buffer provided in this kit with components from other kits.
- Place the soft tip of the swab into the nostril.
- Strictly follow the operating instructions.
- The samples should be tested immediately after collection.
- Children aged 2 to 15 years old should have their samples collected and tested by an adult. Do not use the test for anyone under 2 years of age.
- The test can only be used once.

STORAGE AND STABILITY

- The test can be stored at 2℃-30℃and all reagents are stable until the expiration dates marked on their outer packaging.
- Do not use after expiry.

LIMITATION

- False positive results may occur, particularly in individuals without COVID-19symptoms and/or individuals who live in areas with low numbers of SARS-Cov-2 infections and without known exposure to COVID-19.
- The test is less reliable in the later phase of infection and in asymptomatic individuals.
- Repeat testing within 1 - 3 days is recommended in occupational risk, high risk settings or if there is an ongoing suspicion of infection.
- Negative results may not mean that a person is not infectious and if symptoms are present the person must seek professional medical advice.
- A negative result does not rule out infection with another type of respiratory virus.
- If you have a SARS-CoV-2 POSITIVE result, follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary and the need to seek guidance from your local State or Territory Health Department for reporting of positive results if required, if unwell seek medical assistance.
- If you have a Influenza or RSV POSITIVE result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.
- In the early stages of infection or before symptoms appear, low antigen expression may lead to negative results.
- The test results are related to the quality of the specimen collection, processing, transportation and storage. Any faults can lead to imprecise results. If the cross-contamination is not controlled during specimen processing, false-positive results may occur.
- A positive result cannot necessarily determine if a person is infectious.

SAFETY INFORMATION

- Please dispose of the test materials in a closed plastic bag with the household refuse.
- Wearing a mask can help protect you and those around you if you are in an area with community transmission and physical distancing is not possible.
- Follow the directions of your local state or territory government health department to protect yourself.
- 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 entire test kit should keep out of the reach of children and pets at all times 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.

PERFORMANCE CHARACTERISTICS

Clinical Evaluation
Using RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal) by professional was compared to the RT-PCR kit. The sensitivity is 96.36% (106/110 known confirmed positive) for SARS-Cov-2 and 95.56% (86/90 known confirmed positive) for influenza A and 95% (38/40known confirmed positive) for influenza B and 93.55% (58/62 known confirmed positive) for RSV, the specificity is > 99.9% (480/480 known confirmed negatives) for SARS-Cov-2 and 99.8% (499/500 known confirmed negatives) for influenza A and >99.9% (550/550 known confirmed negatives) for influenza B and >99.9%(528/528 known confirmed negatives) for RSV.

Usability Study
Using RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal) by layperson was compared to the RT-PCR kit. The sensitivity is 97.22% (35/36) for SARS-Cov-2 , 96.67% (30/31) for influenza A, 96.97% (32/33) for influenza B, 96.77%(30/31)for RSV, the specificity is > 99.99% (84/84) for SARS-Cov-2, > 99.99% (90/90) for influenza A, > 99.99% (90/90) for influenza B and > 99.99% (89/89) for RSV.

Variants Information
The following SARS-CoV-2 variants can be detected with RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal): Alpha, Beta, Gamma ,Epsilon, Delta and Omicron.
The following Influenza strains can be detected with RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal) :A/Darwin/6/2021, A/Darwin/9/2021, A/Victoria/2570/2019, Hong Kong/2671/2019, A/Guangdong-Maonan/SWL1536/2019, A/Brisbane/02/2018, A/Michigan/45/2015, A/Victoria/361/2011, A/Texas/50/2012,A/California/7/2009,A/South Australia/34/2019, A/Switzerland/8060/2017, A/Singapore/INFIMH-16-0019/2016,A/Sydney/5/2021,B/Phuket/3073/2013,B/Austria/1359417/2021,B/Washington/02/2019, B/Colorado/06/2017, B/Massachusetts/2/2012.
The following RSV strains can be detected with RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal):A-2,Long,9320,Washington,B-1 wild type.

Limit of Detection (LOD)
The Limit of Detection (LoD) of the RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal) is 625 $TCID_{50}$/mL for SARS-Cov-2, $1.0\times10^{2}TCID_{50}$/mL for Influenza A（H1N1）, $2\times10^{2}TCID_{50}$/mL for Influenza A（H3N2）,$1.0\times10^{3}TCID_{50}$/mL for Influenza B, $2.4\times10^{2}TCID_{50}$/mL for RSV (A-2)and $4.5\times10^{2}TCID_{50}$/mL for RSV(B-1 wild type).

Cross Reaction
SARS-coronavirus; MERS-coronavirus; (SARS-CoV-2); AdenovirusType 1, Type 3, Type 5, Type 7, Type 8, Type 11, Type 18, Type 23, Type 55; Influenza A H1N1 Denver, H1N1 WS/33, H1N1 A/Mal/302/54, H1N1 New Caledonia, H3N2 A/Hong Kong/8/68; Influenza B Nevada/03/2011, B/Lee/40, B/Taiwan/2/62; Respiratory syncytial virus; Legionella pneumophila Bloomington-2, Los Angeles-1, 82A3105; Mycobacterium tuberculosis K, Erdman, HN878, CDC1551, H37Rv; Streptococcus pneumoniae 4752-98 [Maryland (D1)6B-17], 178 [Poland 23F-16], 262 [CIP 104340], Slovakia 14-10 [29055]; Streptococcus pyogenes Typing strain T1[NCIB 11841, SF 130]; Mycoplasma pneumoniae, Mutant 22, FH strain of Eaton Agent [NCTC 10119], 36M129-B7; Coronavirus 229E, OC43, NL63, HKU1; Human Metapneumovirus (hMPV) 3 Type B1Peru2-2002; Human Metapneumovirus (hMPV) 16 Type A1 IA10-2003; parainfluenza virus Type 1, Type 2, Type 3, Type 4; Rhinovirus A16; candida albicansCICC 1965; pseudomonas aeruginosa ATCC9027; staphylococcus epidermis ATCC 14990; Enteroviruse EV68, EV71; chlamydia pneumoniae VR2282; haemophilus influenzae ATCC9006; bordetella pertussis ATCC9340; Pneumocystis jirovecii pneumonia M167-6

The Cross reactive study results show that the SARS-coronavirus affect the test results for SARS-Cov-2 and not affect the test results for Influenza A/B and RSV. The SARS-CoV-2 is not affect the test results for Influenza A/B and RSV. The influenza A is not affect the test results for SARS-CoV-2 and Influenza B and RSV . The influenza B is not affect the test results for SARS-CoV-2 and Influenza A and RSV.The RSV is not affect the test results for SARS-CoV-2 and Influenza A and Influenza B.The kit can detect SARS-CoV-2, Influenza A and Influenza B and RSV in presence of co-infection.

Interfering Substances
When tested using the RSV, Influenza A/B & Covid-19 Rapid Antigen Combo Test (Nasal), 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; Sodium Cromoglycate; Olopatadine Hydrochloride; Zanamivir; Oseltamivir; Artemether-lumefantrine; 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.

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

AUSTRALIAN CAPITAL TERRITORY CORONAVIRUS HELPLINE
☎ 02 5124 9213 Coronavirus helpline (8am to 8pm daily): 02 6207 7244 https://health.act.gov.au/

NEW SOUTH WALES DEPARTMENT OF HEALTH
☎ 1300 066 055 Coronavirus hotline (Service NSW, 24/7): 137 788 https://www.health.nsw.gov.au/

NORTHERN TERRITORY DEPARTMENT OF HEALTH
☎ 08 8922 8044 Coronavirus hotline (National helpline): 1800 020 080 https://health.nt.gov.au/

QUEENSLAND DEPARTMENT OF HEALTH
☎ 13HEALTH or 13 432 584 Coronavirus hotline: 134COVID or 134 268 https://www.health.qld.gov.au/

SOUTH AUSTRALIAN DEPARTMENT OF HEALTH
☎ 1300 232 272 Coronavirus hotline (9am to 5pm daily): 1800 253 787 https://www.sahealth.sa.gov.au/

TASMANIAN DEPARTMENT OF HEALTH
☎ 1300 135 513 Public Health Hotline (coronavirus): 1800 671 738 https://www.health.tas.gov.au/

VICTORIAN DEPARTMENT OF HEALTH
☎ 1300 650 172 Victorian coronavirus hotline (24/7): 1800 675 398 https://www.dhhs.vic.gov.au/

WESTERN AUSTRALIAN DEPARTMENT OF HEALTH
☎ 08 9222 4222 Coronavirus hotline: 13COVID (8am to 6pm, Mon–Fri) or 1800 595 206
https://www.healthywa.wa.gov.au/

SYMBOLS

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

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Number: xxxxxxxxxx
Version: 1.1
Effective Date: 2024-03-13