

# Flu A/B, RSV & COVID-19 Antigen Combo Test Device

(Self-Test)

REF SCFR-44/H005

## INSTRUCTIONS FOR USE

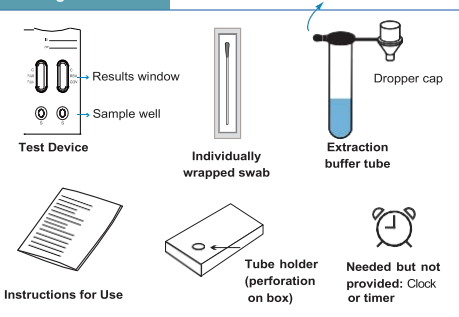
The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is a rapid visual immunoassay for the direct and qualitative detection of SARS-CoV-2, influenza A, influenza B and respiratory syncytial viral antigens from nasal secretions. The test is designed for self-testing use.

**Carefully read the instructions before performing the test. Failure to follow the instructions may result in inaccurate test results.**



Scan QR code to access online tutorial For Customer Support  
Call 1300 565 010 (9am - 7pm AEST/9am - 8pm AEDT, 7 days per week)

### Package Contents



### Storage and Stability

Store the kit at 2-30°C / 36-86°F and protect from direct sunlight. The expiration date of the materials is indicated on the external packaging. Do not freeze the kit.

### Prepare for the Test

1. Check expiration date printed on test.
2. Wash your hands thoroughly.
3. Open the pouch and place the test cassette on a flat surface.
4. Peel off the aluminum foil cover of the extraction buffer.
5. Insert the extraction buffer into the tube holder by punching through the perforation on the box.

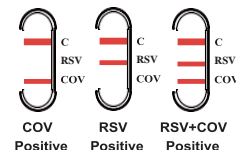
### Test Procedure

1. Open the swab packaging. Remove the swab using the stem.  
**Be careful not to touch the soft, fabric tip of the swab.**
2. Insert the swab about 1/2 to 3/4 inch into the nostril. (Collect the anterior nasal swab specimen).
3. Circle the swab against the nasal wall 5 times.  
**Do not just spin the swab.**
4. Pull the swab out of the nose while rubbing it against the walls and repeat the process with the same swab in the other nostril.  
**WARNING: Inaccurate test results may occur if the nasal swab specimen is not properly collected. Collect specimen and immediately perform test according to instructions.**
5. Place swab into the tube that you previously placed in the tube holder.  
**Note:** With children, the maximum depth of insertion into the nostril may be less than 3/4 of an inch, and you may need a second person to hold the child's head while swabbing.

6. Remove the tube from the tube holder. Rotate the swab while squeezing the lower part of the tube 10-15 times so that a slight pressure is exerted on the tip of the swab.  
**WARNING: Failure to rotate the swab 10-15 times may lead to incorrect results.**
7. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.  
**WARNING: Failure to squeeze the tube can lead to incorrect results due to excess buffer in the swab.**
8. Secure the dropper cap onto the buffer tube.
9. Invert the tube and add 3 drops of the solution to sample well by gently squeezing the tube.  
**WARNING: Do not hold the dropper tube more than 1/4 inch above sample well.**
10. Set a timer and read the results at 15 minutes.  
**WARNING: Adding other than the recommended number of drops may result in inaccurate results.**  
**WARNING: Do not read the result before 15 minutes or after 30 minutes.**  
**Dispose of used kit components and patient samples in household trash.**

### Read and Interpret Your Results

#### For COVID-19&RSV Test -Positive



**COVID-19 positive:** Two coloured lines appear on the membrane. One line appears in the control region (C) and the other line appears in the COV region (COV).  
**RSV positive:** Two coloured lines appear on the membrane. One line appears in the control region (C) and the other line appears in the RSV region (RSV).  
**COVID-19+RSV positive:** One coloured band appears in the control region (C), and two other coloured bands appear in both COV region (COV) and RSV region (RSV).  
If you test positive for COVID-19, stay at home until your symptoms are gone, manage and treat your symptoms as needed, and monitor your symptoms. If your symptoms worsen, see your doctor for oral treatments if you are in a high-risk group. You should follow the advice of your state or territory health agency and avoid visiting high-risk settings such as hospitals and aged and disability care settings. If you experience serious symptoms, such as severe shortness of breath or chest pain, call 000 immediately. A RSV positive test result means that the virus that causes RSV was detected in the patients' sample, and it is very likely that the patient has RSV. If you have a RSV positive result, please consult a medical practitioner for clinical care.

**NOTE:** There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens.

### Read and Interpret Your Results

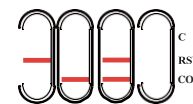
#### For COVID-19&RSV Test-Negative



**Negative:** Only one coloured band appears in the control region (C), and band appears neither in the COV region (COV) nor RSV region (RSV).

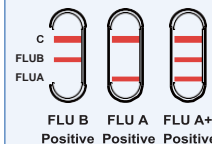
A negative result for COVID-19 does not mean a person does not have COVID-19. If a person has symptoms, they should follow the guidance from the local state or territory health departments, and if unwell seek medical assistance.  
A negative result does not mean a person is not infectious or does not have RSV. If you are unwell, please consult a medical practitioner for follow up care and continue to follow all public health advice on limiting the spread of RSV.  
**NOTE:** Negative results are presumptive and may need to be confirmed with a molecular assay. If symptoms continue or infection is suspected, repeat testing is recommended within 1-3 days as SARS-Cov-2 antigen cannot be precisely detected in all phases of an infection.

#### For COVID-19&RSV Test-Invalid



**Invalid:** No coloured band appears in the control region (C), whether a test band(s) is present or not. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

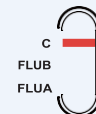
#### For Influenza A&B Test-Positive



**Influenza A Positive:** One coloured band appears in the control region (C), and another coloured band in the FLUA region (FLUA).  
**Influenza B Positive:** One coloured band appears in the control region (C), and another coloured band in the FLUB region (FLUB).  
**Influenza A+B Positive:** One coloured band appears in the control region (C), and two other coloured bands appear in both FLUA region (FLUA) and FLUB region (FLUB).

Co-infection with influenza A and B is rare. The positive results for both A and B should be considered an invalid result, and another test should be performed. If the test is again positive for both influenza A and B, the specimen should be re-tested by another method prior to reporting of results.  
If you test positive or feel unwell, you should consult a medical practitioner for appropriate follow-up care.  
**NOTE:** There is a very small chance that this test can give a result that is incorrect (a false positive). A positive result does not rule out co-infections with other pathogens.

#### For Influenza A&B Test-Negative



**Negative:** Only one coloured band appears in the control region (C), and band appears neither in the FLUA region (FLUA) nor FLUB region (FLUB).

A negative test result means it is unlikely patients have influenza A/B disease. Please continue to observe local hygiene and safety measures.  
**NOTE:** A negative result does not mean a person does not have influenza, and if symptoms persist, the person should seek medical attention and further testing if required.

#### For Influenza A&B Test-Invalid



**Invalid:** No coloured band appears in the control region (C), whether a test band(s) is present or not. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

## INTENDED USE

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is a rapid, visual immunoassay intended for the direct and qualitative detection of nucleoprotein antigens of SARS-CoV-2 (COVID-19), Influenza A, Influenza B, and fusion protein antigen of Respiratory Syncytial Virus (RSV) in nasal swab specimens collected from individuals with respiratory infection symptoms. The test is most effective for detecting SARS-CoV-2 within the first 7 days of symptom onset, and Influenza A/B and RSV within the first 4 days of symptom onset. This test is designed for self-testing purposes. Children aged below 18 years old must be supervised or tested by an adult when carrying out the test. The assay provides a preliminary result that aids in the diagnosis of COVID-19, Influenza A/B, and/or RSV. This test has not been validated for use in asymptomatic individuals.

## PRINCIPLE

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is a qualitative lateral flow immunoassay for the detection of SARS-CoV-2, Influenza A, Influenza B, and RSV antigens. The test results are interpreted visually by the presence or absence of coloured bands on four individual test strips. During testing, viral antigens in the specimen, if present, bind to specific antibodies conjugated with coloured particles. The antigen-antibody complexes migrate along the nitrocellulose membrane by capillary action and are captured by immobilised antibodies in the corresponding test regions, forming visible coloured bands. The control region on each test strip captures excess coloured particles and serves as an internal procedural control, indicating that sufficient specimen has been applied and that the test has functioned correctly. The appearance of a coloured band in a test region indicates a positive result for the corresponding virus, while the absence of a band indicates a negative result.

## QUALITY CONTROL

### Internal Procedural Controls

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device includes built-in procedural controls to verify the proper functioning of the test. Each test strip has an internal control region to ensure the correct flow of the sample through the device. The presence of a coloured band at the "C" (control) line indicates that the test has been performed correctly and the sample has flowed as expected. The user should confirm the appearance of this red control line before interpreting the test results.

## SAFETY PRECAUTIONS AND WARNINGS

- For in vitro diagnostic use only.
- Read the instructions for use thoroughly before use. Follow the directions carefully.
- This test is intended for single use only. Do not reuse any components.
- Use only the provided components from the same kit and do not mix with components from different lots.
- Children aged below 18 years old must be supervised or tested by an adult when carrying out the test.
- Do not use the test on individuals prone to nosebleeds or those who have had facial or head injuries/surgery in the past 6 months.
- Avoid contact of the swab tip with any surface before use and do not touch the swab tip during the collection process.
- Perform the test immediately after collecting the sample. Place the swab into the extraction buffer right after sample collection.
- Do not use the test kit or components if they are expired, damaged, or if the extraction buffer is discoloured or cloudy. This could indicate contamination.
- Wear a safety mask or face-covering when collecting samples from a child or another individual.
- Avoid contact with the extraction buffer, which contains trace

amounts of sodium azide. If skin contact occurs, rinse with plenty of water.

- Keep the test and its components out of the reach of children and pets, both before and after use.
- Dispose of used kit components and patient samples in household trash.
- To avoid incorrect test results, keep foreign substances and household cleaning products away from the test during the testing process.
- Do not interpret the test result before 15 minutes or after 30 minutes of starting the test.
- Ensure adequate volume of extraction reagent is added to the test card by holding the tube vertically, no more than 1 inch above the sample well, and adding drops slowly.

## STORAGE AND STABILITY

- Store the Flu A/B, RSV & COVID-19 Antigen Combo Test Device at 2-30°C/ 36-86°F.
- DO NOT FREEZE.**
- Kit contents are stable until the expiration dates marked on their outer packaging and containers. Once opened the device should be used immediately.

## LIMITATIONS OF THE TEST

- The Flu A/B, RSV & COVID-19 Antigen Combo Test Device is intended for self-testing and in vitro diagnostic use only. It is designed for the qualitative detection of viral antigens specific to SARS-CoV-2, Influenza A virus, Influenza B virus, and Respiratory Syncytial Virus (RSV). The intensity of the colour in the positive bands should not be interpreted as quantitative or semi-quantitative.
- The test can detect both viable and non-viable viruses.
- As with all diagnostic tests, a definitive clinical diagnosis should not be based solely on the results of a single test. Diagnosis should be confirmed by a healthcare professional after considering all clinical and laboratory findings.
- Failure to adhere to the test procedure and result interpretation guidelines may negatively impact test performance and/or invalidate the results.
- Negative results do not rule out the possibility of viral infection and should be confirmed with a molecular assay if clinically indicated.
- A positive test result does not necessarily indicate that an individual is infectious.
- The reliability of the test decreases in the later stages of infection and in asymptomatic individuals.
- False negative results may occur, particularly if testing is performed outside the recommended time frame (within 7 days of symptom onset for SARS-CoV-2 and within 4 days for Influenza A/B and RSV).
- If infection is still suspected, including in high-risk or occupational settings, repeat testing within 1–3 days is recommended.
- A negative result does not rule out infection with another respiratory virus.

## PERFORMANCE CHARACTERISTICS

### COVID-19

Using the Flu A/B, RSV & COVID-19 Antigen Combo Test, results obtained by professionals were compared with RT-PCR as the reference method. The test demonstrated a sensitivity (positive agreement) of 94.9% (94/99 RT-PCR-confirmed positives) and a specificity (negative agreement) of 99.3% (415/418 RT-PCR-confirmed negatives) for COVID-19.

### Influenza A antigen test

Using the Flu A/B, RSV & COVID-19 Antigen Combo Test, results obtained by professionals were compared with RT-PCR as the

reference method. The test demonstrated a sensitivity (positive agreement) of 92.0% (48/52 RT-PCR-confirmed positives) and a specificity (negative agreement) of 98.9% (468/470 RT-PCR-confirmed negatives) for Influenza A.

### Influenza B antigen test

Using the Flu A/B, RSV & COVID-19 Antigen Combo Test, results obtained by professionals were compared with RT-PCR as the reference method. The test demonstrated a sensitivity (positive agreement) of 90.3% (28/31 RT-PCR-confirmed positives) and a specificity (negative agreement) of 99.8% (485/486 RT-PCR-confirmed negatives) for Influenza B.

### RSV antigen test

Using the Flu A/B, RSV & COVID-19 Antigen Combo Test, results obtained by professionals were compared with RT-PCR as the reference method. The test demonstrated a sensitivity (positive agreement) of 93.3% (28/30 RT-PCR-confirmed positives) and a specificity (negative agreement) of 99.8% (488/489 RT-PCR-confirmed negatives) for RSV.

### Usability Study

Lay users of different age distributions, education levels, and genders participated in a usability study conducted in a self-testing environment. Compared with RT-PCR as the reference method, the clinical performance of the Flu A/B, RSV & COVID-19 Antigen Combo Test in the hands of lay persons demonstrated a sensitivity (positive agreement) of 94.9% (37/39) and a specificity (negative agreement) of 100% (157/157) for COVID-19 antigen; a sensitivity of 90.6% (29/32) and a specificity of 100% (164/164) for Influenza A antigen; a sensitivity of 90.6% (29/32) and a specificity of 100% (164/164) for Influenza B antigen; and a sensitivity of 93.5% (29/31) and a specificity of 100% (165/165) for RSV antigen.

### Analytical Sensitivity

Virus Lines	LoD Titer
SARS-CoV-2 (wild type)	1.0x10 <sup>2.4</sup> TCID <sub>50</sub> /mL
B.1.1.7 (Alpha)	1.26x10 <sup>6</sup> TCID <sub>50</sub> /mL
B.1.351 (Beta)	5.71x10 <sup>5</sup> TCID <sub>50</sub> /mL
B.1.617.2 (Delta)	3.16x10 <sup>6</sup> TCID <sub>50</sub> /mL
BA.1 (Omicron)	1.78x10 <sup>6</sup> TCID <sub>50</sub> /mL
BA.2 (Omicron)	1.0x10 <sup>6</sup> TCID <sub>50</sub> /mL
BA.4.1 (Omicron)	6.31x10 <sup>4</sup> TCID <sub>50</sub> /mL
BA.5.2.1 (Omicron)	3.73x10 <sup>4</sup> TCID <sub>50</sub> /mL
BA.2.76 (Omicron)	1.0x10 <sup>5</sup> TCID <sub>50</sub> /mL
JN.1 (Omicron)	4.31x10 <sup>6</sup> TCID <sub>50</sub> /mL
NB.1.8.1 (Omicron)	5.45x10 <sup>4</sup> TCID <sub>50</sub> /mL
KP.3 (Omicron)	2.2x10 <sup>6</sup> TCID <sub>50</sub> /mL
XEC (Omicron)	1.17x10 <sup>5</sup> TCID <sub>50</sub> /mL
Flu A H1N1 (A/Brisbane/02/2018)	1.2x10 <sup>4</sup> TCID <sub>50</sub> /mL
Flu A H1N1 (A/Wisconsin/588/2019)	1.48x10 <sup>4</sup> TCID <sub>50</sub> /mL
Flu A H1N1 (A/Sydney/5/2021)	1.4x10 <sup>4</sup> TCID <sub>50</sub> /mL
Flu A H3N2 (A/Darwin/6/2021)	1.05x10 <sup>4</sup> TCID <sub>50</sub> /mL
Flu A H3N2 (A/Darwin/6/2021)	9.13x10 <sup>3</sup> TCID <sub>50</sub> /mL
Flu B (B/Phuket/3073/2013)	2.5x10 <sup>5</sup> TCID <sub>50</sub> /mL
Flu B (B/Austria/1359417/2021)	4.13x10 <sup>4</sup> TCID <sub>50</sub> /mL
RSV Type A	9.0x10 <sup>3</sup> TCID <sub>50</sub> /mL
RSV Type B	2.4x10 <sup>3</sup> TCID <sub>50</sub> /mL

### Cross Reactivity

The Flu A/B, RSV & COVID-19 Antigen Combo Test Device demonstrated no cross-reactivity with the microorganisms listed below at the specified concentrations. **Only SARS-CoV showed false positive results with the SARS-CoV-2 test, which is expected due to the high genetic homology between SARS-CoV and SARS-CoV-2.**

Microorganisms	
Adenovirus 1	Parainfluenza virus 3
Adenovirus 2	Parainfluenza virus 4
Adenovirus 3	Rhinovirus A30

Adenovirus 4	Rhinovirus B52
Adenovirus 5	MERS-Cov
Adenovirus 7	Bordetella parapertussis
Adenovirus 55	Bordetella pertussis
Epstein-Barr virus	Candida albicans
Enterovirus EV70	Chlamydia pneumoniae
Enterovirus EV71	Group C Streptococcus
Enterovirus A16	Haemophilus influenzae
Enterovirus A24	Legionella pneumophila
Echovirus 6	Mycoplasma pneumoniae
Human coronavirus 229E	Mycobacterium tuberculosis
Human coronavirus OC43	Staphylococcus aureus
Human coronavirus NL63	Staphylococcus epidermidis
Human Metapneumovirus	Streptococcus agalactiae
Norovirus	Streptococcus pneumoniae
Parainfluenza virus 1	Streptococcus pyogenes
Parainfluenza virus 2	Human coronavirus HKU1

Note:

- For SARS-CoV-2 Detection: The SARS-CoV-2 detection in the COV test shows no cross-reactivity with Influenza A virus, Influenza B virus, or Respiratory Syncytial Virus (RSV).
- For Influenza Detection: The FLUA test for Influenza A shows no cross-reactivity with Influenza B virus, Respiratory Syncytial Virus (RSV), or SARS-CoV-2. Similarly, the FLUB test for Influenza B shows no cross-reactivity with Influenza A virus, Respiratory Syncytial Virus (RSV), or SARS-CoV-2.
- For RSV Detection: The RSV test shows no cross-reactivity with Influenza A virus, Influenza B virus, or SARS-CoV-2.

### Interfering Substances













None of the following substances were found to interfere with the performance of the test device.

Substances	
3 OTC nasal sprays	Guaiaacol glyceryl ether
3 OTC mouth washes	Mucin
3 OTC throat drops	Woolen blood
4-acetamidophenol	Mupirocin
Acetylsalicylic acid	Oxymetazoline
Albuterol	Phenylephrine
Chlorpheniramine	Phenylpropanolamine
Dexamethasone	Zanamivir
Dextromethorphan	Adamantanamine
Diphenhydramine	Osetamivir phosphate
Doxylamine succinate	Tobramycin
Flunisolide	Triamcinolone

If you have any questions regarding the use of this product, please call Innovation Scientific self-test product support 1300 565 010 (9am to 7pm AEST/9am to 8pm AEDT) or email [covid19support@innovationsci.com.au](mailto:covid19support@innovationsci.com.au).

Test system problems may also be reported to the TGA through the Users Medical Device Incident Report program (email [iris@health.gov.au](mailto:iris@health.gov.au) or call 1800 809 361).

## GLOSSARY OF SYMBOLS

 IVD	 In vitro diagnostic	 Manufacturer	 Caution
 Instructions for use	 Do not re-use	 Number of tests	 Use by date
 Temperature limit	 Lot	 Batch code	 Catalog number

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