

For IVD Use Only

Quick Reference Instructions For self-testing

Fast result in 10 minutes | Nasal Test



A rapid test for the qualitative detection of influenza A virus, influenza B virus, COVID-19, human metapneumovirus, respiratory syncytial virus and adenovirus antigen in nasal swab specimens by self-testing.

STEP 1 PREPARATION

1 Wash your hands.



2 Check the kit contents before testing.



Test cassette	Extraction tube	Sterile swab	Instructions for Use & Quick Reference Instructions	Workstation
1 Test / 1 pcs	1 Test / 1 pcs	1 Test / 1 pcs	1 Test / 1 pcs	1 Test / 1 pcs
5 Tests / 5 pcs	5 Tests / 5 pcs	5 Tests / 5 pcs	5 Tests / 1 pcs	5 Tests / 1 pcs
25 Tests / 25 pcs	25 Tests / 25 pcs	25 Tests / 25 pcs	25 Tests / 25 pcs	25 Tests / 1 pcs

Materials required but not provided: Timer

3 Check the expiry date shown on the foil pouch packaging. Check that the test cassette inside is intact and that it contains one test strip framed within the result window. Please use it within one hour after unpacking the foil pouch.

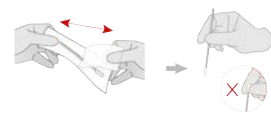


STEP 2 SAMPLE COLLECTION

4 Place the extraction tube in the workstation.

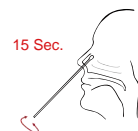


5 Open the sterile swab pouch and hold the swab.



! Do not touch swab tip when handling swab sample.

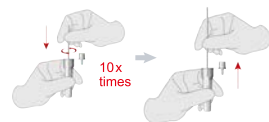
6 Instructions for the nasal swab procedure
Insert the entire tip of the swab two to three centimetres into the left nostril. Rub the inside of the nostril in a circular motion for at least 15 seconds. Remove the swab and insert it into the right nostril. Swab the inside of the nostril in a circular motion for at least 15 seconds.



! Do not soak the swab in the extraction tube or other liquid before inserting the swab into the nose.

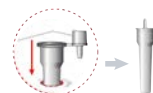
STEP 3 TEST PROCEDURE

7 Place the swab in the extraction tube. Rotate the swab for at approximately 15 seconds and stir for 10+ times while pushing the swab tip against the sides of the tube to squeeze out the solution from the swab.



! Test kit solutions should only be used as directed; do not ingest; avoid contact with skin and eyes; keep out of the reach of children and pets before and after use. If the extraction buffer comes in contact with the skin or eyes, flush with plenty of water. If irritation persists, seek medical advice from a doctor or your local medical centre.

8 Screw the cap onto the extraction tube and make sure it is firmly in place.



9 Cover the tube with cap, then add all of the sample into the sample hole vertically.



! Squeeze out all of the sample solution in the extraction tube.

10 Read the test results in 10-15 minutes.

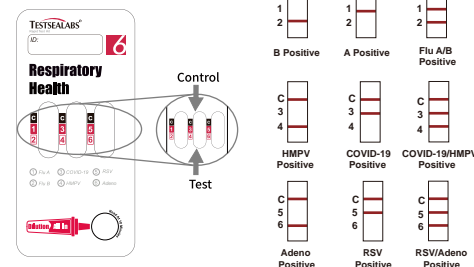


! Do not read test results after 15 minutes.

11 Carefully wrap the used test kit components and swab samples, dispose in normal household waste.



STEP 4 INTERPRETATION OF TEST RESULT



What to do if POSITIVE:

- If you have a POSITIVE result, staying at home protects the people in your community and you should not visit high-risk settings like hospitals and aged and disability care settings.
- If you feel unwell or need advice for someone in your care, talk with your health provider, or speak to a nurse by calling the healthdirect helpline on 1800 022 222.
- If you develop symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately.
- Multiple test lines showing coloration indicate infection with multiple viruses.

Interpretation of Flu A/B Positive Results:

Control line (C) and at least one test line appear on the membrane. The appearance of (1) test line indicates the presence of Flu A antigen. The appearance of (2) test line indicates the presence of Flu B antigen. And if both (1) and (2) test lines appear, it indicates that the presence of both Flu A and Flu B antigen. Lower the antigen concentration is, the weaker the result line is.

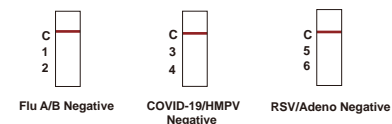
Interpretation of COVID-19/HMPV Positive Results:

Control line (C) and at least one test line appear on the membrane. The appearance of (3) test line indicates the presence of COVID-19 antigen. The appearance of (4) test line indicates the presence of HMPV antigen. And if both (3) and (4) test lines appear, it indicates that the presence of both COVID-19 and HMPV antigen. Lower the antigen concentration is, the weaker the result line is.

Interpretation of RSV/Adenovirus Positive Results:

Control line (C) and at least one test line appear on the membrane. The appearance of (5) test line indicates the

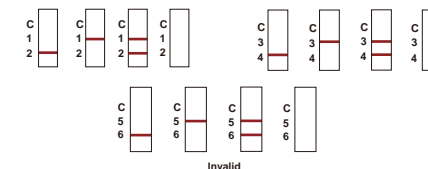
presence of RSV antigen. The appearance of (6) test line indicates the presence of Adenovirus antigen. And if both (5) and (6) test lines appear, it indicates that the presence of both RSV and Adenovirus antigen. Lower the antigen concentration is, the weaker the result line is.



What to do if NEGATIVE:

- If symptoms persist, advice to conduct repeat testing and seek professional medical advice.
- Repeat testing (e.g. within 1-3 days) if there is an ongoing suspicion of infection, being in a high risk setting or where there is an occupational risk or other requirement.
- The tests are less reliable in the later phase of infection.

Negative: One colored line appears in the control region (C). No apparent colored line appears in the test line region.



What to do if INVALID:

- This may be caused by insufficient specimen volume or incorrect procedural technique. Please review the instructions and repeat the test using a new device. If the issue persists, discontinue use of the test kit and contact your local distributor.
- Invalid:** If the control line fails to appear in any of the three detection windows, the test result is considered invalid.

Australia Sponsor: Sonitec Pty Ltd
Address: U211/17 Chisholm St, Wollli Creek NSW 2205
Customer Support Number: 02 8328 1008
Hours: 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), Mon-Fri
Email: info@sonitec.com.au
Website: www.sonitec.com.au/pages/6-in-1

Contact the TGA to report poor performance or usability issues
email iris@health.gov.au or call 1800 809 361



Manufactured by

Hangzhou Testsea Biotechnology Co., Ltd.
No.13-2 Guanshan Road, Yuhang District,
311115 Hangzhou, Zhejiang, China
Web: www.testsealabs.com

Electronic IFU and instructional video



Flu A/B + COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette (Nasal Swab)

For IVD Use Only

Fast result in 10 minutes | Nasal Test



INTENDED USE

Flu A/B+COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette (Nasal Swab) is an immunochromatographic test intended for the qualitative detection of influenza A virus, influenza B virus, SARS-CoV-2, human metapneumovirus (HMPV), respiratory syncytial virus (RSV), and adenovirus antigens in nasal swab specimens. The test is intended to be performed by laypersons as a self-testing rapid test to aid in detection of infection in individuals suspected of infection with SARS-CoV-2 (COVID-19) within the first 7 days of symptom onset, and influenza A/B, HMPV, RSV, or adenovirus within the first 4 days of symptom onset.

PRINCIPLE

The Flu A/B + COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette(Nasal Swab) is a qualitative membrane strip based immunoassay for the detection of influenza A virus, influenza B virus, COVID-19 virus, human metapneumovirus, respiratory syncytial virus and adenovirus antigen in nasal swab specimens. In this test procedure, influenza A antibody, influenza B antibody, COVID-19 antibody, HMPV antibody, RSV antibody and adenovirus antibody, is immobilized in the different test line regions of the device. After a nasal swab specimen is placed in the specimen well, it reacts with influenza A antibody, influenza B antibody, COVID-19 antibody, HMPV antibody, RSV antibody and adenovirus antibody, coated particles that have been applied to the specimen pad. This mixture migrates chromatographically along the length of the test strip and interacts with the immobilized influenza A antibody, influenza B antibody, COVID-19 antibody, human metapneumovirus antibody, respiratory syncytial virus antibody and adenovirus antibody. If the specimen contains influenza A virus, influenza B virus, COVID-19 virus, human metapneumovirus, respiratory syncytial virus, adenovirus antigen. A colored line will appear in the corresponding test line region indicating a positive result. If the specimen does not contain influenza A virus, influenza B virus, COVID-19 virus, human metapneumovirus, respiratory syncytial virus, adenovirus antigen, a colored line will not appear in these regions indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

graphically along the length of the test strip and interacts with the immobilized influenza A antibody, influenza B antibody, COVID-19 antibody, human metapneumovirus antibody, respiratory syncytial virus antibody and adenovirus antibody. If the specimen contains influenza A virus, influenza B virus, COVID-19 virus, human metapneumovirus, respiratory syncytial virus, adenovirus antigen. A colored line will appear in the corresponding test line region indicating a positive result. If the specimen does not contain influenza A virus, influenza B virus, COVID-19 virus, human metapneumovirus, respiratory syncytial virus, adenovirus antigen, a colored line will not appear in these regions indicating a negative result. To serve as a procedural control, a colored line will always appear at the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains influenza A antibody, influenza B antibody, COVID-19 antibody, HMPV antibody, RSV antibody and adenovirus antibody as the capture reagent, another influenza A antibody, influenza B antibody, COVID-19 antibody, HMPV antibody, RSV antibody and adenovirus antibody as the detection reagent. A goat anti-mouse IgG antibody is employed in the control line system.

PRECAUTIONS

1. For self-testing in vitro diagnostic use only. Do not use after expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents.
4. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of specimens.
5. Follow standard biosafety guidelines for handling and disposal of potential infective material.
6. Humidity and temperature can adversely affect results.

7. Test can only be performed by person over 18 years age. Any persons or children under 18 years will require adult supervision or assistance. Not to be performed on children under 2 years of age.
8. The test results are less reliable in the late stages of infection.
9. If you are suspected of having a persistent infection, are in a high-risk environment, or are at occupational risk, repeat the test within 1-3 days.
10. The solution in the test kit should only be used as directed; do not swallow; do not immerse the swab in the provided solution or other liquids before inserting it into the nasal cavity.
11. Avoid contact with skin and eyes. Keep out of reach of children and pets before and after use.
12. If the extraction buffer comes into contact with the skin or eyes, immediately rinse with large amounts of water. If irritation symptoms persist, consult a physician or local healthcare facility.

STORAGE AND STABILITY

Store as packaged in the sealed pouch at room temperature or refrigerated (4-30°C or 40-86°F). The test device is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored line appearing in the control region(C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique. Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

Relative Sensitivity: 94.00% (95%CI*:83.45%-98.75%)
Relative Specificity: >99.99% (95%CI*:99.70%-100.00%)
Total Agreement: 99.76% (95%CI*:99.31%-99.95%)

Sensitivity and Specificity of HMPV

The HMPV test was compared with a nucleic acid detection kit.

Method	Nucleic Acid Detection Kit			Total
	Results	Positive	Negative	
Flu A/B+COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette	Positive	62	0	62
	Negative	5	1209	1214
Total		67	1209	1276
Agreement		92.54%	>99.99%	99.61%

Relative Sensitivity: 92.54% (95%CI*:83.44%-97.53%)
Relative Specificity: >99.99% (95%CI*:99.70%-100.00%)
Total Agreement: 99.61% (95%CI*:99.09%-99.87%)

Usability study:

A high level of usability across diverse age groups and education levels. Layperson-operated tests demonstrated high concordance with both professional testing and RT-PCR reference results. Laypersons are able to correctly interpret co-infection (multi-positive) test results for the Flu A/B+COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette(Nasal Swab) when relying on the instructions for use. The Flu A/B+COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette(Nasal Swab) is suitable for self-testing by laypersons.

Method	Nucleic Acid Detection Kit			Total
	Results	Positive	Negative	
Influenza A Test	Positive	55	0	55
	Negative	3	883	886
Total		58	883	941
Agreement		94.83%	>99.99%	99.68%

Relative Sensitivity: 94.83% (95%CI*:85.62%-98.92%)
Relative Specificity: >99.99% (95%CI*:99.58%-100.00%)
Total Agreement: 99.68% (95%CI*:99.07%-99.93%)

Method	Nucleic Acid Detection Kit			Total
	Results	Positive	Negative	
Influenza B Test	Positive	73	0	73
	Negative	6	862	868
Total		79	862	941
Agreement		92.41%	>99.99%	99.36%

Relative Sensitivity: 92.41% (95%CI*:84.20%-97.16%)
Relative Specificity: >99.99% (95%CI*:99.57%-100.00%)
Total Agreement: 99.36% (95%CI*:98.62%-99.77%)

Method	Nucleic Acid Detection Kit			Total
	Results	Positive	Negative	
COVID-19 Test	Positive	62	0	62
	Negative	6	866	872
Total		75	866	941
Agreement		92.00%	>99.99%	99.36%

Relative Sensitivity: 92.00% (95%CI*:83.40%-97.01%)
Relative Specificity: >99.99% (95%CI*:99.57%-100.00%)
Total Agreement: 99.36% (95%CI*:98.62%-99.77%)

Method	Nucleic Acid Detection Kit			Total
	Results	Positive	Negative	
HMPV Test	Positive	46	0	46
	Negative	6	889	895
Total		52	889	941
Agreement		88.48%	>99.99%	99.36%

Relative Sensitivity: 88.46% (95%CI*:76.55%-95.65%)
Relative Specificity: >99.99% (95%CI*:99.59%-100.00%)
Total Agreement: 99.36% (95%CI*:98.62%-99.77%)

Method	Nucleic Acid Detection Kit			Total
	Results	Positive	Negative	
RSV Test	Positive	32	0	32
	Negative	2	907	909
Total		34	907	941
Agreement		94.12%	>99.99%	99.79%

Relative Sensitivity: 94.12% (95%CI*:80.32%-99.28%)
Relative Specificity: >99.99% (95%CI*:99.59%-100.00%)
Total Agreement: 99.79% (95%CI*:99.23%-99.97%)

Method	Nucleic Acid Detection Kit			Total
	Results	Positive	Negative	
Adeno Test	Positive	29	0	29
	Negative	2	910	912
Total		31	910	941
Agreement		93.55%	>99.99%	99.79%

Relative Sensitivity: 93.55% (95%CI*:78.58%-99.21%)
Relative Specificity: >99.99% (95%CI*:99.60%-100.00%)
Total Agreement: 99.79% (95%CI*:99.23%-99.97%)

Interfering Substances

The following compounds have been tested using the Flu A/B+COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette(Nasal Swab) and no interference was observed.

Substances	Substances
Whole Blood	Oxymetazoline
Mucin	Phenylephrine
Budesonide Nasal Spray	Rebetol
Dexamethasone	Relenza
Flunisolide	Tamiflu
Mupirocin	Tobramycin

Cross-reactivity

The Flu A/B+COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette(Nasal Swab) has been tested for other virus (Table below). The results showed no cross-reactivity and they do not intersect. There is no cross-infection between influenza A, influenza B, SARS-CoV-2, human metapneumovirus, syncytial virus, and adenovirus.

No cross-reactivity	Human Rhinovirus 14	Arcanobacterium m	Staphylococcus aureus
Human coronavirus OC-43	Human Rhinovirus 16	Candida albicans 3147	Staphylococcus epidermidis
Human coronavirus NL63	Measles	Corynebacterium pneumoniae	Streptococcus pneumoniae
Pseudomonas aeruginosa	Mumps	Escherichia coli	Streptococcus pyogenes
Nisseria subflava	Parainfluenza virus 2	Moraxella catarrhalis	Streptococcus salivarius
Human Rhinovirus 2	Human parainfluenza virus 3	Neisseria lactamica	Streptococcus sp group F
Coronavirus 229E	Coronavirus HKU-1	Parainfluenza virus 1	Parainfluenza virus 4
MERS Coronavirus Recombinant Protein	Enterovirus EV68	Legionella pneumophila	Bordetella pertussis
Mycoplasma pneumoniae			

Inclusivity Study:

Influenza A	A/Victoria/2570/2019	H2N2 A/Darwin/6/2021
A/Columbia/07/2009(H1N1)	A/Guangdong/Moonan/SW1536/2019	H2N2 A/Darwin/9/2021
A/PR/8/34/TC adapted (H1N1)	A/Brisbane/02/2018	H1N1 A/Sydney/5/2021
A/Hong Kong/8/68(H2N2)	A/Michigan/45/2015	A/South Australia/34/2019
A/Singapore/INM/16-1001/2016	A/Switzerland/90/60/2017	
Influenza B	B/Phuket/3073/2013 (B/Yamagata lineage)	B/Washington/02/2019 (B/Victoria lineage)
B/Wisconsin/1/2010(BX-41/Yamagata lineage)	B/Colorado/06/2017(B/Victoria/2/87 lineage)	B/Massachusetts/2/2012
B/Florida/78/2015(Victoria lineage)	B/Austria/13594/17/2021 (B/Victoria Lineage)	
COVID-19	heat-inactivated SARS-CoV-2 Variant B.1.1.7	SARS-CoV-2, Delta Variant Strain
SARS-Related Coronavirus 2	SARS-CoV-2 Variant B.1.351 Strain	SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.5, Omicron Variant Culture Fluid (Heat Inactivated)
HMPV	HMPV A2	HMPV B2
HMPV A1	HMPV B1	

LIMITATIONS

1. This test detects both viable (live) and non-viable, SARS-CoV, COVID-19, human metapneumovirus, respiratory syncytial virus, adenovirus, FLU A/B antigen. Test performance depends on the amount of virus (antigen) in the sample and may or may not correlate with viral culture results performed on the same sample.
2. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test.
3. The performance of Flu A/B + COVID-19/HMPV+RSV/Adeno Antigen Combo Test Cassette was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test.
4. False negative results may occur if a specimen is improperly collected, transported, or handled.
5. False results may occur if specimens are tested past 1 hour of collection. Specimen should be tested as quickly as possible after specimen collection.
6. Positive test results do not rule out co-infections with other pathogens
7. Positive test results do not differentiate between SARS-CoV and COVID-19 antigen.
8. Negative test results are not intended to rule in other viral or bacterial infections.
9. Negative results, from patients with symptom onset beyond seven days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
10. If the differentiation of specific COVID-19 virus, human metapneumovirus, respiratory syncytial virus, adenovirus, influenza A virus, influenza B virus antigen is needed, additional testing, in consultation with local public health departments, is required.

RSV	RSV B WW/14617/85	RSV 9320
RSV A2	RSV Long	RSV Washington

Adeno	Adenovirus 2	Adenovirus 4
Adenovirus 1	Adenovirus 3	Adenovirus 7
Adenovirus 55		

LOD Study:

Name	Subtype	LOD
Influenza A	A/Columbia/07/2009(H1N1)	10TCID ₅₀ /ml
	A/PR/8/34/TC adapted(H1N1)	25TCID ₅₀ /ml
	A/Hong Kong/8/68(H2N2)	50TCID ₅₀ /ml
	H2N2 A/Darwin/9/2021	50TCID ₅₀ /ml
	H1N1 A/Sydney/5/2021	25TCID ₅₀ /ml
Influenza B	B/Florida/78/2015(Victoria lineage)	200TCID ₅₀ /ml
	B/Wisconsin/1/2010(BX-41A/Yamagata lineage)	100TCID ₅₀ /ml
	B/Phuket/3073/2013 (B/Yamagata lineage)	100TCID ₅₀ /ml
	B/Colorado/06/2017(B/Victoria/2/87 lineage)	200TCID ₅₀ /ml
	SARS-Related Coronavirus 2(Wild-type)	50TCID ₅₀ /ml
COVID-19	heat-inactivated SARS-CoV-2 Variant B.1.1.7 (Alpha)	500genome copies/ml
	SARS-CoV-2 Variant B.1.351 Strain(Beta)	500genome copies/ml
	SARS-CoV-2, Delta Variant Strain	500genome copies/ml
	SARS-Related Coronavirus 2 (SARS-CoV-2) Lineage BA.5, Omicron Variant Culture Fluid (Heat Inactivated)	100TCID ₅₀ /ml
	Human metapneumovirus A1	100TCID ₅₀ /ml
HMPV	Human metapneumovirus B2	100TCID ₅₀ /ml
	Human respiratory syncytial virus A	300TCID ₅₀ /ml
RSV	Human respiratory syncytial virus B	300TCID ₅₀ /ml
	Human adenovirus 1	1000TCID ₅₀ /ml
Adeno	Human adenovirus 3	1000TCID ₅₀ /ml
	Human adenovirus 7	1000TCID ₅₀ /ml
	Human adenovirus 3	1000TCID ₅₀ /ml

	Do not re-use		IVD In vitro diagnostic medical device
	Manufacturer		Temperature limit
	Consult instructions for use or consult electronic instructions for use		Do not use if package is damaged and consult instructions for use
	Catalogue number		Batch Code
	Use-by date		Contains Sufficient for <v> Tests
	Keep away from sunlight		Keep dry
	Date of Manufacture		Caution



Hangzhou Testsea Biotechnology Co., Ltd. No.13-2 Guanshan Road, Yuhang District, 311115 Hangzhou, Zhejiang, China Web: www.testsealabs.com

Sponsor: Sonitec Pty Ltd U21117 Chisholm St, Wollri Creek NSW 2205 02 828 1008 9 am and 7 pm (AEST), or 9 am and 8 pm (AEDT), Mon-Fri info@sonitec.com.au Web: www.sonitec.com.au/pages/6-in-1