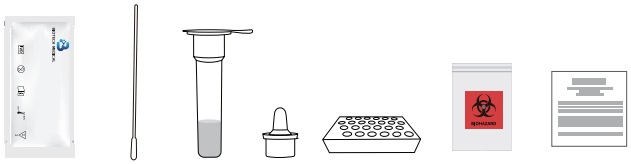
BIOTECH MEDICAL

Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit

FOR SELF-TESTING.
FOR *IN VITRO* DIAGNOSTIC USE ONLY.
Before testing,please read the instructions carefully.

Before testing, please scan the QR code to watch the instructional video.

TEST COMPONENTS



Each test kit contains (a) test cassette(s), (a) disposable sterile swab(s), extraction solution (in (a) sealed tube(s)), (a) tube tip(s), a tube stand ,(a) Biohazard bag (s)and instructions for use.

Component	Package			
	VISIRA-757H (1T/Kit)	VISIRA-757H (2T/Kit)	VISIRA-757H (5T/Kit)	VISIRA-757H (25T/Kit)
Test cassette	1	2	5	25
Disposable sterile swab	1	2	5	25
Tube containing extraction solution	1	2	5	25
Tube tip	1	2	5	25
Tube stand	/	/	1	1
Instructions for use	1	1	1	25
Biohazard bag	1	2	5	25

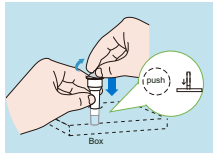
Note : Boxes containing one or two tests can be used as a tube stand.
Materials required but not provided: timer.

SPECIMEN COLLECTION AND PREPARATION

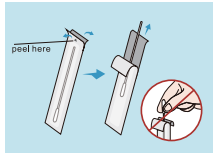
Note:

1. Bring the test cassettes and extraction solution to room temperature (15-30°C) prior to testing.1 test/kit and 2 tests/kit, the tube stand can be used by pressing the dotted line holes on the box, 5 test/kit and 25 tests/kit, the tube stand provided inside the box.
2. Consider any materials of human origin as potentially infectious anid handle them carefully. Keep the tube vertical during the entire procedure.
3. Nasal swab specimens are recommended to be tested within8 hours at up to 30 °C or 72 hours at 2-8 °C after collection. Extracted nasal sample solutions are recommended to be tested within 4 hours at up to 30 °C, 24 hours at 2-8 °C, or may be stored at-70°C for upto 30 days prior to testing. These conditions support specimen integrity and ensure reliable test performmance within the intended use.
4. For children and adolescents between the ages of 3-16, it is recommended that the test be carried out by a parent/guardian.

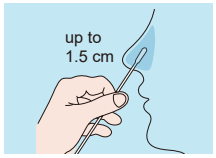
Wash your hands with soap and dry them, or use hand sanitiser before testing.



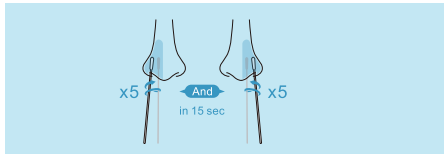
Open the tube containing extraction solution and place the tube in the tube stand.



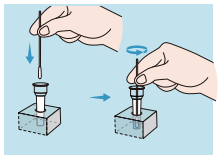
Remove the swab from its packaging. Do not touch the disposable sterile swab tip.



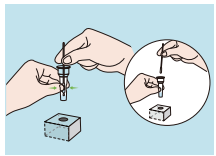
Gently insert the tip of the swab into the nostril until resistance is met (up to 1.5 cm).



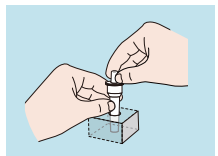
Rotate the swab 5 times against the nasal wall. Using the same swab, repeat the same process in the other nostril to ensure that an adequate specimen volume is collected from both nasal cavities. It is important to obtain as much secretion as possible.



Insert the swab with the collected specimen into the tube containing extraction solution. Swirl the swab 5 times while pressing the tip of the swab against the bottom and sides of the tube.

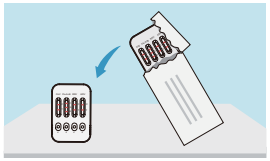


Remove the swab while squeezing the sides of the tube to extract liquid from the swab. Try to squeeze out as much liquid as possible.

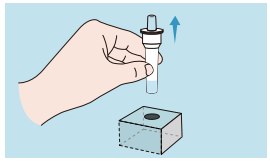


Securely attach the tube tip to the tube.

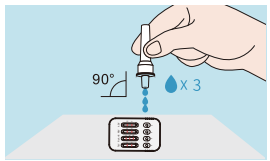
TEST PROCEDURE



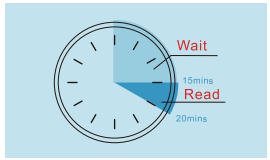
Remove the test cassette from its sealed foil pouch and put it on a clean and level surface.



Remove the tube from the tube holder.



Invert the extraction solution tube so that the tube tip is pointing downwards. Holding it vertically, gently squeeze the tube to dispense 3 drops of the extracted specimen into each of the four specimen wells on the test cassette. Avoid the formation of air bubbles.

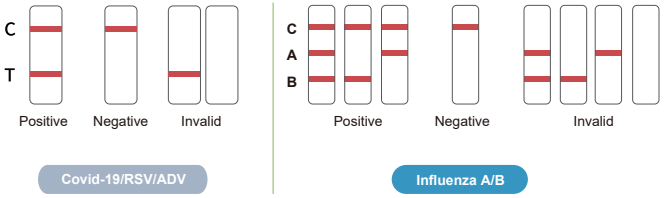


Read the test result after 15 minutes. Do not interpret the test result after more than 20 minutes.

Dispose of the used device in biohazard bag.

INTERPRETATION OF TEST RESULTS

"C": Control Line "T": Test Line "A": Influenza A Test Line "B": Influenza B Test Line



Positive result

For Covid-19 / RSV / Adenovirus :
Both the quality control line (C) and the detection line (T) appeaT

For Influenza A&B :
Positive influenza A antigen:
Both the quality control line (C) and the influenza A detection line appear, while the influenza B detection line does not appear.
Positive influenza B antigen:
Both the quality control line (C) and the influenza B detection line appear, while the influenza A detection line does not appear.
Positive influenza A and B antigen:
All 3 lines appear, including the quality control line (C) aand the influenza A and influenza detection lines.

What to do?
If the test result is positive, it is currently suspected to be a resppiratory infection. The possibility of a false positive result from this testing method is extremely low. Ifyour test result is positive or you are feeling unwell, you should stay at hoome for self-isolation or consult a dor for treatment to prevent the spread of thee infection to others

Negative result

For Covid-19 / RSV / Adenovirus :
Only the quality control line (C) appears, with no other line appearing on the detection line

For Influenza A&B :
Only the quality control line (C) appears, with no other line appearing on the influenza A and influenza B detection line. It indicates the test result isnegative for both influer za A and influenza B antigens.

What to do?
If the test result is negative, it does not mean there is no respiratory infection. If you still feel unwell, it is recommended to seek medical assistance for further toesting

Invalid Result

For Covid-19 / RSV / Adenovirus :
Quality control line (C) fails to appear indicating the test is invaalid, no matter if the detection line appears or not. Collect a new specimen and perfoorm another test with a new test device

For Influenza A&B :
Quality control line (C) fails to appear indicating the test is invallid, no matter if the influenza A or influenza B detection line appears or not. Collect a new specimen and perform another test with a new test device.

What to do?
If the test result is invalid, the user should retest with a rew test

INTENDED USE

The Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit is a rapid chromatographic immunoassay for the qualitative detection of Covid-19, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV) and Adenovirus antigens in nasal swab specimens. The test is not automated. It is an in-vitro diagnostic rapid test intended for use as an aid in the diagnosis of a Covid-19, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV) and Adenovirus infection in individuals with typical symptoms, such as fever, a dry cough, fatigue, nasal congestion, a runny nose, sore throat, etc., as well as in asymptomatic subjects.
This product is suitable for self-testing. The test cannot be used as the sole basis for the diagnosis or exclusion of an infection with Covid-19, Influenza A, Influenza B, Respiratory Syncytial Virus (RSV) and Adenovirus, and cannot provide information on the status of an infection.

PRINCIPLE

Covid-19 Rapid Test has one line of anti-Covid-19 antibody on the detection line (T line) and one quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated anti-Covid-19 antibody on the detection line. If the specimen contains Covid-19 antigen, the detection line will appear red indicating the Covid-19 antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.
Influenza A+B Rapid Test has one line of anti-influenza A antibody on the detection line (A line), one line of anti-influenza B antibody on the detection line (B line) and one quality control line (C line). When the specimen is added to the specimen well, it will react with the labeled antibody to form a complex; the mixture then migrates through the membrane by capillary action and interacts with the coated anti-influenza A antibody and anti-influenza B antibody on the detection line. If the specimen contains influenza A or influenza B antigen, the detection line will appear red indicating the presence of influenza A or influenza B antigen. Otherwise, the test result will be negative. The test device also contains the quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.
RSV Rapid Test has one line of anti-RSV antibody on the detection line (T line) and one quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated anti-RSV antibody on the detection line. If the specimen contains RSV antigen, the detection line will appear red indicating the RSV antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.
Adenovirus Rapid Test has one line of anti-Adeno antibody on the detection line (T line) and one quality control line (C line). When extracted specimen is added to the specimen well, it will react with the labeled antibody to form a complex, the mixture then migrates through the membrane by capillary action and interacts with the coated anti-Adeno antibody on the detection line. If the specimen contains Adeno antigen, the detection line will appear red indicating the Adeno antigen is positive. Otherwise, the test result will be negative. The test device also contains a quality control line C which should appear red for all valid tests. If the quality control line C does not appear, the test result will be invalid even if the detection line appears.

STORAGE AND STABILITY

1.Store the test kit in a cool, dry place between 36-86°F (2-30°C). Keep away from light. Exposure to temperature and / or humidity outside the specified conditions may cause inaccurate results.
2.Do not freeze. Use the test kit at temperatures between 59-86°F (15-30°C).
3.Use the test kit between 10-90% humidity.
4.Do not use the test kit beyond the expiration date (printed on the foil pouch and box).
Note: *All expiration dates are printed in Year-Month-Day format. 2022-06-18 indicates June 18, 2022.*

WARNINGS AND PRECAUTIONS

1.For *in vitro* diagnostic use only.
2.This package insert must be read completely before performing the test. Failure to follow the insert gives inaccurate test results.
3.Do not open the sealed pouch unless ready to conduct the assay.
4.Do not use expired devices.
5.Bring all reagents to room temperature (15°C-30°C) before use.
6.Do not use the components in any other type of test kit as a substitute for the components in this kit.
7.Wear disposable gloves while handling the kit reagents and clinical specimens. Wash hands thoroughly after performing the test.
8.Do not smoke, drink, or eat in areas where specimens or kit reagents are being handled.
9.Dispose of all specimens and materials used to perform the test as biohazardous waste.

LIMITATIONS

1.This test is for *in vitro* diagnostic use only and cannot be re-used.
2.The used test should be treated as potentially infectious materials and should be disposed of properly.
3.The test kit should be kept away from direct sunlight, moisture and heat.
4.Please check if the test kit has any damage and check the expiry date before use.
5.The sample volume will affect the accuracy of the test result. Inaccurate sample volume may cause a false positive or negative result.
6.Test results must be evaluated in conjunction with other clinical data available to the physician.
7.Positive test results do not rule out co-infections with other pathogens.
8.Positive and negative predictive values are highly dependent on prevalence. The local prevalence should be taken into consideration when interpreting diagnostic test results.
9.Please be very careful when collecting nasal swab specimen from children.
10.Components from different batches are not allowed to be used in combination.

QUALITY CONTROL

An internal procedural control is included in the test cassette. A coloured line appearing in each control line region (C) is an internal procedural control. It indicates sufficient specimen flow and that the test is functioning properly.
A positive control is not provided with the device, and external controls are available for separate purchase. Positive Control：Zeptometrix SARS-Related Coronavirus 2 (SARS-CoV-2) Culture Fluid (Heat Inactivated); Zeptometrix Influenza A virus Cluture Fluid; Zeptometrix Influenza B virus Cluture Fluid; Zeptometrix RSV-A Culture Fulid(Heat Inactivated) and Zeptometrix Adenovirus Type 3 Culture Fluid.

PERFORMANCE

1. Clinical Sensitivity/Clinical Specificity
Nasal swab specimens were collected from symptomatic patients. The performance of the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit was compared to a commercially available molecular assay.

Table 1 - Covid-19 Performance of the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit as Compared to PCR Test

Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit (for Covid-19)	PCR		
	Positive	Negative	Total
Positive	96	0	96
Negative	4	650	654
Total	100	650	750
Sensitivity	96% (96/100, 95%CI, 90.07%~98.90%)		
Specificity	100% (650/650, 95%CI, 99.43%~100%)		
Accuracy	99.47% (746/750, 95%CI, 98.64%~99.85%)		

Table 2 - Influenza A Performance of the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit as Compared to PCR Test

Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit (for Influenza A)	PCR		
	Positive	Negative	Total
Positive	96	0	96
Negative	5	649	654
Total	101	649	750
Sensitivity	95.05% (96/101, 95%CI, 88.82%~98.37%)		
Specificity	100% (649/649, 95%CI, 99.43%~100%)		
Accuracy	99.33% (745/750, 95%CI, 98.45%~99.78%)		

Table 3 - Influenza B Performance of the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit as Compared to PCR Test

Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit (for Influenza B)	PCR		
	Positive	Negative	Total
Positive	101	0	101
Negative	1	648	649
Total	102	648	750
Sensitivity	99.02% (101/102, 95%CI, 94.66%~99.98%)		
Specificity	100% (648/648, 95%CI, 99.43%~100%)		
Accuracy	99.87% (749/750, 95%CI, 99.26%~100%)		

Table 4 - RSV Performance of the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit as Compared to PCR Test

Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit (for RSV)	PCR		
	Positive	Negative	Total
Positive	97	0	97
Negative	4	649	653
Total	101	649	750
Sensitivity	96.04% (97/101, 95%CI, 90.17%~98.91%)		
Specificity	100% (649/649, 95%CI, 99.43%~100%)		
Accuracy	99.47% (746/750, 95%CI, 98.64%~99.85%)		

Table 5 - Adenovirus Performance of the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit as Compared to PCR Test

Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit (for Adenovirus)	PCR		
	Positive	Negative	Total
Positive	67	6	73
Negative	1	676	677
Total	68	682	750
Sensitivity	98.53% (67/68, 95%CI, 92.08%~99.96%)		
Specificity	99.12% (676/682, 95%CI, 98.1%~99.68%)		
Accuracy	99.06% (743/750, 95%CI, 98.09%~99.62%)		

2. Limit of Detection/ Cut-off
The limit of detection (LoD) of the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit was established in dilution studies performed with one Covid-19 strain, two influenza A strains, two influenza B strains, one RSV strain and one Adenovirus strain using the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit. The LoD represents the concentration of Covid-19/influenza A+B virus/RSV/Adenovirus that produces consistently positive results >95% of the time. The approximate LoD concentrations identified for each strain tested are listed in the table below.

Viral Strain	LoD ($TCID_{50}$/mL)
Covid-19	75.5
Influenza A Puerto Rico/8/1934 (H1N1)	2.13×10^2
Influenza A Wisconsin/67/2005 (H3N2)	5.21×10^3
Influenza B Brisbane/60/2008 (B/Victoria lineage)	5.85×10^2
Influenza B Phuket/3073/2013 (B/Yamagata lineage)	1.31×10^3
RSV	2.34×10^2
Adenovirus	4.17×10^2

3. Hook Effect
No high-dose hook effect was observed when testing Covid-19, influenza A&B and RSV as well as Adenovirus viral strains at the concentrations listed below using the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit.

Viral strain	Concentration（$TCID_{50}$/mL）
Covid-19	1.51×10^6
Influenza A Puerto Rico /8/1934 (H1N1)	1.70×10^5
Influenza A Wisconsin/67/2005 (H3N2)	4.17×10^5
Influenza B Brisbane/60/2008 (B/Victoria lineage)	1.17×10^5
Influenza B Phuket/3073/2013 (B/Yamagata lineage)	1.05×10^6
RSV	4.68×10^4
Adenovirus	4.17×10^5

4. Cross-reactivity
Potential cross-reactivity and microbial interference with the following microorganisms was evaluated using the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit. No cross-reactivity or microbial interference was observed with the pathogens listed below.
Human coronavirus 229E, human coronavirus OC43, human coronavirus NL63, human coronavirus HKU1, MERS-coronavirus, parainfluenza virus, rhinovirus A16, *Legionella pneumophila*, *Mycobacterium tuberculosis*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, *Staphylococcus aureus*, human metapneumovirus, enterovirus, *Haemophilus influenza, Candida albicans*, *Bordetella pertussis*, *Staphylococcus epidermidis*, *Pneumocystis jirovecii* and pooled human nasal wash.
5. Interfering Substances
The following substances showed no interference with the Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kit:
HAMA.
Anti-viral drugs: Zanamivir, Oseltamivir, Artemether/Lumefantrine, Lamivudine, Ribavirin, Daclatasvir.
Antiparasitic medication: Quinine
Respiratory specimens: Mucin from bovine submaxillary gland, type I-S; EDTA-anticoagulated human blood; biotin; Nasal mucus.
Nasal sprays or drops: Neosynephrine®, Afrin® Nasal Spray, saline nasal spray.
Allergy relief medicine: Zicam® Allergy Relief Nasal Gel, sodium cromoglycate, olopatadine hydrochloride.
Anti-inflammatory medication: Paracetamol (Acetaminophen), acetylsalicylic acid, ibuprofen.
Antibiotics: Mupirocin, tobramycin, erythromycin, ciprofloxacin, doxycycline hyclate.
6. Reproducibility
The reproducibility study was performed by two operators using three lots of Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kits at three different sites over three non-consecutive days. The study included two runs per day, with six replicates of each sample per run. Each run was performed by a different operator. The intra-assay agreements were 100%. The inter-site agreement was 100%.
7. Repeatability
The repeatability study was performed by two operators using three lots of Covid-19/Influenza A & B/RSV/ADV Rapid Antigen Test Kits over five non-consecutive days. The study included two runs per day, with two replicates of each sample per run. Each run was performed by a different operator. The intra-assay agreements were 100%.
Report Performance or Usability Issues:
If you encounter poor performance or usage problems during self-testing, please contact TGA by calling 1800 809 361 to report.You can also report the issue through User Medical Device Incident Report, email: iris@health.gov.au.

REFERENCES

1. Seynaeve, Ysaline et al. “Evaluation of Two Rapid Antigenic Tests for the Detection of Covid-19 in Nasopharyngeal Swabs.” Journal of clinical medicine vol. 10,13 2774. 24 Jun. 2021.
2. Lim, Ho-Jae et al. “Evaluation of Multiplex Rapid Antigen Tests for the Simultaneous Detection of Covid-19 and Influenza A/B Viruses.” Biomedicines vol. 11,12 3267. 9 Dec. 2023.
3. Zhang, Naru et al. “Recent advances in the detection of respiratory virus infection in humans.” Journal of medical virology vol. 92,4 (2020): 408-417.
4. Trabelsi, A et al. “Evaluation of four methods for rapid detection of adenovirus.” European journal of clinical microbiology & infectious diseases: official publication of the European Society of Clinical Microbiology vol. 11,6 (1992): 535-9.

INDEX OF SYMBOLS

	Consult instructions for use		Use by	Σ	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only	LOT	Lot number	REF	Catalog number
30°C 2°C	Storage temperature limitations		Manufacturer		Do not reuse
	Date of manufacture				

Australian Sponsor:
Starshine Media Pty Ltd
Trading as Biotech Medical Supplies
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Greenacre NSW 2190 Australia
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Phone: 02 8604 8362
Website: www.biotechmedicalsupplies.com.au

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