Getein

IVD

SARS-CoV-2/Influenza A/B Antigen Rapid Self-Test Kit

User Manual for self-testing

INTENDED USE

SARS-CoV-2/Influenza A/B Antigen Rapid Test Kit is intended for the qualitative detection of nucleocapsid protein antigen from SARS-CoV-2/Influenza A/B in human nasal swab samples from individuals within seven days of symptom onset for COVID-19 and within four days of symptom onset for Influenza A / B.

This test is used for self-test.SARS-CoV-2/Influenza A/B Antigen Rapid Self-Test Kit is an aid in the differentiate of patients with suspected SARS-CoV-2/Influenza A/Influenza B infection in conjunction with clinical symptoms and result of other diagnostic methods. Results from the test should not be used as the sole basis for diagnosis and exclusion of SARS-CoV-2/Influenza A/Influenza B/ infection.

STORAGE AND STABILITY

Store the test kit at 4-30℃ with a valid period of 24 months.

Use the test card within 1 hour once the foil pouch is opened.

Note: Do not use the kit after the date of expiration indicated on the package.

PRINCIPLE

SARS-CoV-2/Influenza A/B Antigen Rapid Self-Test Kit is an immunochromatographic membrane assay that uses highly sensitive antibodies to detect SARS-CoV-2, influenza A and influenza B nucleocapsid protein from nasal swab samples.

The samples will move by capillary action when are added to the test card, and SARS-CoV-2/Influenza A/B antigens, if present in the sample, will react with the colored anti-SARS-CoV-2/influenza A/ influenza B antibodies on test line and form antigen-antibody complexes. These complexes appears red on each test line. To serve as a procedure control, a red line will always appear in the control line region after proper volume of sample has been added.

PRECAUTIONS

1. Do not open pouches until ready to perform the test to protect the test cards from getting damp exposing in air for too long.
2. The test cards can be stored in room temperature with sealed pouches.
3. Always keep the kit out of the reach of children. Small parts of the kit can be a choking hazard.
4. Sample extraction solution is a phosphate buffer contained low concentration of sodium chloride, tween, hexadecyl trimethyl ammonium bromide and sodium azide. If extraction solution splashes your body or into eyes, please wash with water.

INTERNAL CONTROL DESCRIPTION

A procedural internal control is built in the 'control line (C)' of the device when a colored line appears in the control region ("C line"). It confirms sufficient specimen volume and correct procedural technique.

LIMITATIONS

1. The test is for in vitro diagnostic use only.
2. False negative results may occur if the level of antigen in sample is below the detection limit of the test, testing is not performed within the first 7 days of symptom onset or the sample was collected incorrectly.
3. False positive results are more likely to occur when COVID-19/Flu A/Flu B prevalence in the community is low (i.e. <0.5%) or in high prevalence settings.
4. Clinical diagnosis and treatment cannot be made without consulting with the physician.
5. The tests are less reliable in the later phase of infection and in asymptomatic individuals.
6. Repeat testing within 1-3 days if ongoing suspicion of infection, high risk setting or occupational.
7. Negative results may not mean that a person is not infectious and if symptoms are present the person must seek immediate further testing.
8. A negative result does not rule out infection with another type of respiratory virus.
9. If a positive result is obtained and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
10. It's a presumptive test only and follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
11. This test can only be used once.
12. The kit cannot differentiate between SARS-coronavirus and SARS-CoV-2 Virus.
13. The product SARS-CoV-2/Influenza A/B Antigen Rapid Self-Test Kit showed no drop off in sensitivity when compared with the wild type with respect to the following variants-Delta and Omicron. We will keep evaluating the impact of new variants.

PERFORMANCE CHARACTERISTICS

1. Limit of Detection (LoD)

The LoD for nasal swab was established using inactivated SARS-CoV-2, Influenza A (H1N1 A/Florida/3/2006, H3N2 A/Hong Kong/8/68), Influenza B (Victoria Lineage B/Florida/78/2015, Yamagata Lineage B/Florida/4/2006) isolate strain. The strain was spiked with negative human nasal swab into a series of concentrations. The estimated LoD found from the initial two-fold serial dilution test was confirmed by testing 20 replicates. The confirmed LoD for SARS-CoV-2/Influenza A/ Influenza B were as follows.

Virus Strains	#Positive/#Total	LoD
SARS-CoV-2	19/20	200 $TCID_{50}$/mL
Influenza A H1N1 A/Florida/3/2006	19/20	32.5 $TCID_{50}$/mL
Influenza A H3N2 A/Hong Kong/8/68	19/20	12.2 $TCID_{50}$/mL
Influenza B Victoria Lineage B/Florida/78/2015	19/20	52.5 $TCID_{50}$/mL
Influenza B Yamagata Lineage B/Florida/4/2006	19/20	6.85 $TCID_{50}$/mL

2. Clinical Agreement Study

For SARS-CoV-2:

For 247 cases of PCR positive, the Relative Sensitivity of the test is 97.57% (241/247).

For 267 cases of PCR negative, the Relative Specificity of the test is 99.63% (266/267).

For 247 cases of PCR positive and 267 cases of PCR negative, the Relative Accuracy of the test is 98.64% (507/514).

For Influenza A:

For 64 cases of PCR positive, the Relative Sensitivity of the test is 96.88% (62/64).

For 254 cases of PCR negative, the Relative Specificity of the test is 99.61% (253/254).

For 64 cases of PCR positive and 254 cases of PCR negative, the Relative Accuracy of the test is 99.06% (315/318).

For Influenza B:

For 52 cases of PCR positive, the Relative Sensitivity of the test is 94.23% (49/52).

For 266 cases of PCR negative, the Relative Specificity of the test is 99.62% (265/266).

For 52 cases of PCR positive and 266 cases of PCR negative, the Relative Accuracy of the test is 98.74% (314/318).

3. Usability Study

In supervised results interpretation research, 100% (100/100) of the lay persons could be able to correctly understand the instructions for use and read the different results of test cards. In diagnostic sensitivity non-supervised and diagnostic specificity non-supervised researches, 160 participants were enrolled and self-tested with package insert only. The test results are 98.75% (158/160) for SARS-CoV-2, 99.38% (159/160) for Influenza A, 99.38% (159/160) for Influenza B.

4. Analytical Specificity

1) Cross-Reactivity & Microbial Interference

Each organism and virus was tested in triplicate in the absence and presence of SARS-CoV-2, Influenza A and Influenza B respectively. According to the test results, there was no cross-reactivity with the following viruses or organisms.

For SARS-CoV-2:

Viruses or organisms		
Human coronavirus 229E	Influenza A	Bordetella pertussis
Human coronavirus OC43	Influenza B	Mycoplasma pneumoniae
Human coronavirus NL63	Enterovirus	Chlamydia pneumoniae
MERS coronavirus	Respiratory syncytial virus	Legionella pneumophila
Adenovirus (e.g. C1 Ad. 71)	Rhinovirus	Mycobacterium tuberculosis
Human Metapneumovirus (hMPV)	Haemophilus influenzae	Pneumocystis jirovecii
Parainfluenza virus Type 1	Streptococcus pneumoniae	Pseudomonas Aeruginosa
Parainfluenza virus Type 2	Streptococcus pyogenes	Staphylococcus Epidermidis
Parainfluenza virus Type 3	Candida albicans	Streptococcus Salivarius
Parainfluenza virus Type 4a	Pooled human nasal wash	Human coronavirus HKU1
Epstein Barr Virus		

For Influenza A and Influenza B:

Viruses or organisms		
Bordetella pertussis	Neisseria subflava	Epstein Barr Virus
Canidida albicans	Pseudomonas aeruginosa	Human parainfluenza type 1
Chlamydia trachomatis	Staphylococcus epidermidis	Human parainfluenza type 2
Corynebacterium diphtheriae	Streptococcus pneumoniae	Human parainfluenza type 3
Escherichia coli	Streptococcus pyogenes	Measles
Haemophilus influenzae	Streptococcus salivarius	Human metapneumovirus
Lactobacillus plantarum	Adenovirus type 1	Mumps virus
Legionella pneumophila	Adenovirus type 7	Respiratory syncytial virus
Moraxella catarrhalis	Human coronavirus (OC43)	type A
Mycobacterium tuberculosis (avirulent)	Human coronavirus (229E)	Respiratory syncytial virus
Mycoplasma pneumoniae	Human coxsackievirus	type B
Neisseria meningitidis	Cytomegalovirus	Rhinovirus type 1B
SARS-coronavirus	SARS-CoV-2	

2) Interferences

The potentially interfering substances that may be found in the upper respiratory tract in subjects (including over the counter medications). No false positive or false negative results were seen at the following interfering substances.

For SARS-CoV-2:

Potentially Interfering Substances		
Blood (human)	Zicam Cold Remedy	Tamiflu (Oseltamivir phosphate)
Mucin	Homeopathic (Alkalol)	Biotin
Naso GEL (NeilMed)	Sore Throat Phenol Spray	Methanol
CVS Nasal Drops (Phenylephrine)	Tobramycin	Diphenhydramine
Afrin (Oxymetazoline)	Mupirocin	Dextromethorphan
CVS Nasal Spray (Cromolyn)	Fluticasone	Dexamethasone

For Influenza A and Influenza B:

Potentially Interfering Substances		
Whole Blood (human)	CVS Nasal Drops (Phenylephrine)	Sore Throat Phenol Spray
Mucin	Afrin (Oxymetazoline)	Tobramycin
Ricola (Menthol)	CVS Nasal Spray (Cromolyn)	Mupirocin
Sucrets (Dyclonin/Menthol)	Zicam Cold Remedy	Fluticasone
Chloraseptic (Menthol/Benzocaine)	Homeopathic (Alkalol)	Tamiflu (Oseltamivir
Naso GEL (NeilMed)	Fisherman's Friend	Phosphate)

DESCRIPTION OF SYMBOLS USED

Key to symbols used			
	Manufacturer		Use-by date
	Do not re-use		Date of manufacture
	Consult instructions for use	LOT	Batch code
	Temperature limit	IVD	In vitro diagnostic medical device
	Contains sufficient for <n> tests		Do not use if package is damaged
	Keep away from sunlight		Keep dry
REF	Catalogue number		Biological risks
	For self-testing		

Getein Biotech, Inc.
Add: No.9 Bofu Road, Luhe District, Nanjing, 211505, China
Tel: +86-25-68568508
Fax: +86-25-68568500
E-mail: tech@getein.com.cn overseas@getein.com.cn
Website: www.getein.com

CONTACT INFORMATION

For assistance regarding the use of the product or for reporting any issues associated with the performance of the test call 1300 593 089.
This service is available between 9 am and 7 pm (AEST) 7 days per week.

Australian Sponsor / Distributor :
Nationwide Asset Management Consolidated Pty Limited
Address: 600 St Kilda Rd Melbourne Vic 3004 Australia
P.O. BOX 6009 Melbourne 3004 Vic Australia
E-mail : support@getein.com.au
Web:www.getein.com.au
Telephone: 1300 593 089

IMPORTANT CONTACTS

In the event you are experiencing problems with the test, please contact Nationwide Asset Management Consolidated Pty Limited.

Reporting scheme, email iris@tga.gov.au or call 1800 809 361.
To contact your local state/territory health department click on the following link: https://www.health.gov.au/about-us/contact-us/local-state-and-territory-health-departments
Testing locations can be found by calling the numbers below or visiting these websites.
Australian Capital Territory Department of Health
General Enquiries: 02 5124 9213
Coronavirus helpline (8am to 8pm daily) :02 6207 7244
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)
Website: https://www.healthywa.wa.gov.au/

Version: WCG93-TGAZ-DXF-S4-04
Last Edition: 18/04/2024

Test Kit Contents						
Catalogue number	CG20670	CG20672	CG20675	CG20710	CG20715	CG20720
Specification	1 Test/kit	2 Tests/kit	5 Tests/kit	10 Tests/kit	15 Tests/kit	20 Tests/kit
SARS-CoV-2/ Influenza A/B Antigen test card	1	2	5	10	15	20
Extraction tube with sample extraction solution and tip	1	2	5	10	15	20
Kit bag	1	2	5	10	15	20
User manual	1	1	1	2	3	4
Sterile swab	1	2	5	10	15	20

Please Scan Me

Customer Support Helpline

Call 1300 593 089

For Information On The Correct Use Of This Test And For Interpretation Of The Test Results.

Customer Service Hours; (24 / 7)

Getein

SARS-CoV-2/Influenza A/B Antigen Rapid Self-Test Kit

Quick Guide

- **For use with nasal swab samples.**
- **For in vitro diagnostic use (IVD) only.**
- **Please read the instruction for use carefully before using the test.**

BEFORE TESTING

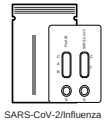
Read the instruction for use carefully. Watch the operation video online if you need more help.

Immediately before starting the test, clean and dry a flat surface to place the test kit on.

Wash your hands thoroughly for 20 seconds, using soap and warm water or hand sanitiser. If doing more than one test, clean the surface and rewash your hands between each test.

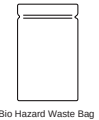
PREPARE FOR TEST

Check the test expiration date printed on the packaging. Check your test components. The test kit contains:



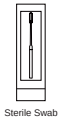
SARS-CoV-2/Influenza A/B Antigen Test Card

Extraction Tube With Sample Extraction Solution & Tip

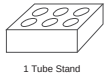


Bio Hazard Waste Bag

User manual (IFU)



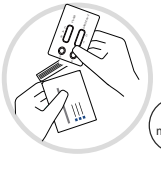
Sterile Swab



1 Tube Stand (For 20 Tests)

Note: If you notice anything damaged, broken or missing, do not use the test kit.

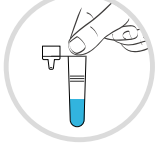
SET UP THE TEST



Take the test card out of the sealed bag and place it onto a clean flat surface.

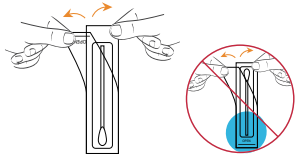
Note: Once opened, start the test within 60 minutes.

Remove the lid from the top of the extraction tube with sample extraction solution.



Place the extraction tube in the holder hole(attached inside the box) to avoid spilling the liquid.

PROCESS SAMPLE



Peel open the swab packaging only when you are ready to use. Gently take out the swab and avoid touching the fabric tip.

Note: Never touch the soft, fabric tip of the swab or you will need to start again with a fresh swab.

Gently insert the tip of the swab into one nostril.Do not insert the swab more than 1.5 cm into your nose.

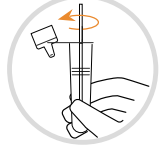
right nostril left nostril

Rotate the swab around the inside wall of your nostril at least 4 times. Repeat the same process with the same swab in the other nostril.

Note: Adults aged 18 and over: Perform full self-testing and report with assistance if needed. Adolescents aged 12 to 17: Self-test (including self-swab) under adult (≥18 years old) supervision. Children aged 2 to 12: Tested by an adult (≥18 years old).

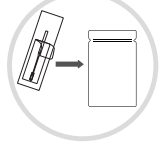
START TEST

For best performance, place the swab in extraction solution as soon as possible after swabbing the nostrils.



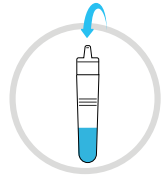
Insert the swab after sampling into the extraction tube and rotate the swab 10 times

Squeeze the swab tip along the inner wall of the extraction tube 3 times.

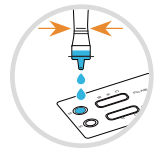


Discard the swab in kit bag.

Put the lid of extraction tube on tightly.



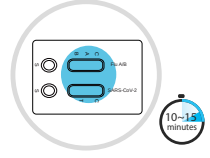
2~3 drops



Gently squeeze the extraction tube and add 2~3 drops of solution into the both sample wells(S).

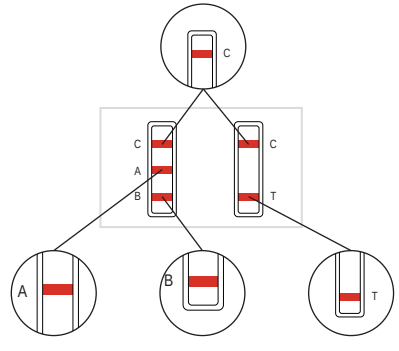
Note:
- Ensure the test kit is on a clean and flat surface.
- Do not move the strip during the test.
- Make sure that you are dropping liquid and not an air bubble.

Set a timer and wait 10~15 minutes before you read your result.



INTERPRET RESULT

Look carefully for C line here.



Look carefully for A, B and T line here.

		T line	A line	B line	Illustration
Valid results-Positive results	SARS-CoV-2 positive	+	-	-	
	SARS-CoV-2 +Influenza A positive	+	+	-	
	SARS-CoV-2 +Influenza B positive	+	-	+	
	SARS-CoV-2 +Influenza A+ Influenza B positive	+	+	+	
	Influenza A positive	-	+	–	
Valid results-Positive results	Influenza A+ Influenza B positive	-	+	+	
	Influenza B positive	-	-	+	
Valid results-Negative results	Negative	-	-	-	
Invalid results	Any other results				

Note: "+" means positive, "-" means negative.

What should I do if I get any of the above results:

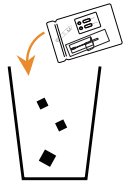
Positive result: Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Negative Result: Continue to follow all applicable rules and protective measures when contacting with others. You might still be infected with SARS-CoV-2 even if the test result is negative. If you still suspect that you have been infected despite a negative test result, repeat the test after 1-2 days or follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.

Invalid Result: Read the instructions again and test with a new test card. If the same situation appears, please stop using this batch of products and contact Nationwide Asset Management Consolidated Pty Ltd (Tel:1300 593 089)

DISPOSAL OF THE TEST KIT

Put all of the used test kit contents in the kit bag provided and put this in trash. Wash your hands thoroughly after disposal.



Before testing, scan the QR code to watch the how to use video, or visit **https://www.getein.com.au/one-step-test-for-flua-flub-sars-cov-2-antigen-colloidal-gold.html**

Please Scan Me

Customer Support Helpline
Call 1300 593 089
For Information On The Correct Use Of This Test And For Interpretation Of The Test Results.
Customer Service Hours; (24 / 7)