Influenza A+B/COVID-19 Antigen Test Kit User Manual

(Dry Color Latex Immunoassay)

For Self-testing Use

[PRODUCT NAME]

Influenza A+B/COVID-19 Antigen Test Kit (Dry Color Latex Immunoassay)

[PACKAGE SPECIFICATION]

1 pc/bag, 5 pcs/bag, 20 pcs/Kit, 25 pcs/Kit

REF	Specification	Test Strip	Nasal Swabs	Prefilled Buffer Kit	IFU
0904-11	1 pc/bag	1	1	1	1
0904-12	5 pcs/bag	5	5	5	1
0904-13	20 pcs/kit	20	20	20	4
0904-14	25 pcs/kit	25	25	25	25

[INTENDED USE]

Influenza A+B/COVID-19 Antigen Test is an immunochromatographic assay for rapid, qualitative detection of SARS- CoV- 2 nucleocapsid & Influenza A & Influenza B antigen antigen in human nasal samples.from individuals suspected of coronavirusinfection disease (COVID-19) within the first seven days of the onset of symptoms or Influenza infection disease within the first four days by lay person. The test is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19) or Influenza infection disease, which is caused by 2019-nCoV or Influenza A /Influenza B antigen.

The test provides preliminary test results. Negative results cannot exclude 2019-nCoV or Influenza infection and they cannot be used as the sole basis for treatment or other management decision.

This test is intended for Self-Testing by persons aged 18 years or above and also for an adult testing another person under 18 years of age. Individuals over 65 years of age should consider to seek assistance in performing the test.

Based on the usability verification report, the availability of Lansion Influenza A+B/COVID-19 Antigen Test Kit(Dry Color Latex ImmunoasFeY). meets the acceptance criteria.

For self-testing use.

[TEST PRINCIPLE]

Influenza A+B/COVID-19 Antigen Test Kit uses the principle of antigen-antibody reaction. The testing specimen will migrate forward due to capillary action, then the analyte of the specimen will combine with antibody which is attached to dyed microspheres (red). This marked complex is attached to the detection area of immobilized antibody and the other dyed microspheres (blue)are attached to the control area. After the detection time, judge negative or positive according to the line on the test strip.

[MATERIALS REQUIRED BUT NOT PROVIDED]

1. Clock, timer or stopwatch 2. Disposable gloves

[STORAGE AND VALIDITY]

Store the test kit at 4°C-30°C, with a valid period of 18 months.

Test strip is individually packaged. Test strip should be used within 1hour once the foil pouch is opened.

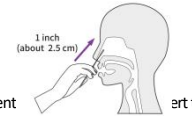
The reagent can be transported at room temperature for a short time. In hot summer and winter, some protective measures should be taken to avoid high temperature or freezing and thawing.

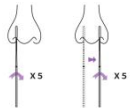
[OPERATION STEPS]

1. Preparation

Please read the instruction carefully before operation. Then wash hands and remove accessories in the test kit. Tear off the sealing film on the upper part of the tube.

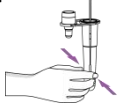
2. Sample collection





Gent ert the swab into one nostril of the pa uld be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times or more along the mucosa inside the nostril. Using the same swab, repeat this process for the other nostril.

3. Sample Treatment



Insert the swab into the tube as soon as possible, slowly squeeze near the bottom of the Sample Extraction Tube 5 times, each lasting 2 seconds.

Remove the Swab while squeezing the bottle of the tube to remove the liquid from the swab. Press the cap firmly onto the tube containing the processed sample.

4. Test

15 minutes

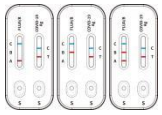
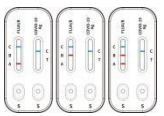
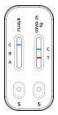
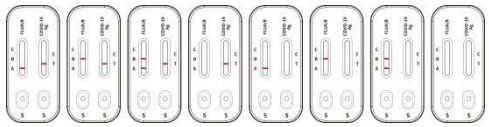
Hold the extraction tube vertically and add 4 drops of treated sample in each sample port.

Reaction Time: 15 minutes.

Do not handle or move the strip until the 15 minutes is complete. Read the results.

Note: The test is intended to be read at 15 minutes. If the test is read before this or is read more than 5 minutes after the indicated read time, results may be inaccurate (false negative, false positive, invalid) and the test should be repeated.

[INTERPRETATION OF RESULT]

<table>
<tr><td>Negative</td><td colspan="3">If only C line appears, the test result is negative (as in the following case).
  </td></tr>
<tr><td>Positive</td><td>COVID-19&Flu Positive</td><td>Flu Positive</td><td>COVID-19 Positive</td></tr>
<tr><td></td><td>If C line, T line, A line and/or B line appear, the test results are positive for both COVID-19 and influenza (as in the following case).
  </td><td>If C line, A line and/or B line appear, the test results are positive for influenza and negative for COVID-19 (as in the following case).
  </td><td>If only the C and T lines appear, the test results are positive for COVID-19 and negative for influenza (as in the following case).
  </td></tr>
<tr><td>Invalid</td><td colspan="3">If no C line appears, the test is invalid (as in the following case).
  </td></tr>
</table>

Negative

- Continue to comply with all applicable rules regarding contact with others and protective measures
- Negative results do not rule out infection, particularly in those who have been in contact with patients.
- If it is suspected, repeat the test after 1-2 days, as the coronavirus cannot be precisely detected in all phases of an infection
- If you are experiencing COVID-19 or influenza symptoms, you must follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary and if unwell seek medical assistance for SARS-CoV-2 positives, and with Individuals with a positive result or who are unwell are advised to consult with a medical practitioner for follow-up clinical care for Influenza A and/or Influenza B positive results.

Note: For the detection of novel coronavirus and possible subtypes (mutant strains), the changes of epitopes caused by mutation sites of Nucleocapsid Protein may reduce the analytical sensitivity of the reagent and lead to false negative results.

Positive

- ***There is a suspicion of COVID-19 ,Flu A or Flu B***
- ***For COVID-19 positives:Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary and if unwell seek medical assistance***
- ***For Influenza A and/or Influenza B positive result: Individuals with a positive result or who are unwell are advised to consult with a medical practitioner for follow-up clinical care***
- ***Continue to comply with all applicable rules regarding contact with others and protective measures***

Invalid

- Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date.
- It is recommended to repeat test with a new test kit.
- If the test results are still invalid, contact a doctor or a testing center for a laboratory PCR test
- If symptoms persist, you should self-isolate at home and avoid contact with others prior to the re-test

•Report repeated invalid results to the sponsor

[WARNINGS AND PRECAUTIONS]

1. IVD For in vitro diagnostic use only.
2. The test device should remain in the sealed pouch until use.
3. Do not use kit past its expiration date.
4. Swabs, tubes, and test devices are for single use only.
5. Do not interchange or mix components from different kit batches.
6. Testing should only be performed using the swabs provided within the kit.
7. To obtain accurate results, do not use visually bloody or overly viscous samples.
8. Wear appropriate personal protection equipment and gloves when running each test and handling patient specimens.
9. Specimens must be processed as indicated in the sample collection and test procedure of this user manual. Failure to follow the instructions for use can result in inaccurate results.
10. Patient swabs, used test strips and used extraction tube may be potentially infectious which should be established with local regulatory requirements.
11. Dispose of test strip and materials as biohazardous waste in accordance with federal, state, and local requirements.
12. Store the test kit out of reach of pets and children, avoid contact of the buffer with the skin and eyes.

[PRODUCT PERFORMANCE]

A. Sensitivity and Specificity

The COVID-19 and Influenza A+B Antigen Combo Rapid Test (Nasopharyngeal Swab) has been evaluated with specimens obtained from the patients. RT-PCR (Nasopharyngeal Swab) is used as the reference method for the COVID-19 and Influenza A+B Antigen Combo Rapid Test (Nasopharyngeal Swab). Specimens were considered positive if RT-PCR (Nasopharyngeal Swab) indicated a positive result. Specimens were considered negative if RT-PCR (Nasopharyngeal Swab) indicated a negative result.

For 2019-nCoV

Influenza A+B/COVID-19 Antigen Test	PCR		Total
	Positive	Negative	
COVID-19 Antigen Positive	227	8	235
COVID-19 Antigen Negative	3	351	354
Total	230	359	589
Sensitivity	96.6%		
Specificity	99.2%		
Total agreement	98.1%		

For Influenza A

Influenza A+B/COVID-19 Antigen Test	PCR		Total
	Positive	Negative	
Influenza A Positive	75	3	78
Influenza A Negative	3	1152	1155
Total	78	1155	1233
Sensitivity	96.2%		
Specificity	99.7%		
Total agreement	99.5%		

For Influenza B

Influenza A+B/COVID-19 Antigen Test	PCR		Total
	Positive	Negative	
Influenza B Positive	45	3	48
Influenza B Negative	4	345	349
Total	49	348	397
Sensitivity	93.8%		
Specificity	98.9%		
Total agreement	98.2%		

B. Cross-reactivity

For 2019-nCoV

Cross-reactivity of the Influenza/2019-nCoV Antigen Combo Test was evaluated by using specimens containing the antigens listed below. The results showed no cross reactivity with the following:

Virus/Bacteria/Parasite✕	Cross-Reactivity Yes/No
Human coronavirus HKU1	No
Human coronavirus 229E	No
Human coronavirus OC43	No
Human coronavirus NL63	No
Influenza A	No
Influenza B	No
Respiratory syncytial virus	No
MERS-coronavirus	No
Adenovirus	No
Human Metapneumovirus	No
Parainfluenza virus 1	No
Parainfluenza virus 2	No
Enterovirus D68	No
Rhinovirus	No
Hemophilus influenza	No
Mycoplasma pneumoniae	No

For Influenza A and Influenza B

To determine the analytical specificity (cross-reactivity) of the Influenza/2019-nCoV Antigen Combo Test, 27 commensal and pathogenic microorganisms (16 bacteria, and 11 viruses) that may be present in the nasal cavity were tested. All of the following microorganisms were negative when tested at concentrations ranging from 10^5 to 10^8 $TCID_{50}$/mL (viruses), 10^7 to 10^8 organisms/mL (bacteria). The results are shown below.

Bacteria	Viruses
Bacteria Viruses	Adenovirus
Chlamydia pneumoniae	Coronavirus
Escherichia coli	Cytomegalovirus (CMV)
Haemophilus influenzae	Human influenza type B virus
Lactobacillus casei	Human influenza type C virus
Moraxella catarrhalis	Mumps virus
Neisseria meningitidis	Parainfluenza 1
Neisseria sicca	Parainfluenza 2
Pseudomonas aeruginosa	Parainfluenza 3
Staphylococcus aureus	Respiratory syncytial virus (RSV)
Staphylococcus epidermidis	Rhinovirus
Streptococcus, Group A	
Streptococcus, Group **B**	
Streptococcus, Group C	
Streptococcus, Group F	
Streptococcus pneumoniae	

C. Limit of Detection

Virus strain	Limit of Detection (LoD)
SARS-CoV-2	1×10^2 $TCID_{50}$/mL
Influenza A H1N1	8×10^3 $TCID_{50}$/mL
Seasonal Influenza H1N1	2×10^4 $TCID_{50}$/mL
Influenza A H3N2	4.8×10^3 $TCID_{50}$/mL
Influenza A H7N9	3×10^3 $TCID_{50}$/mL
Influenza B Victoria	1×10^3 $TCID_{50}$/mL
Influenza B Yamagata	3.7×10^4 $TCID_{50}$/mL

[LIMITATION]

1. The etiology of respiratory infection caused by microorganisms other than Influenza A+B and SARS-CoV-2 will not be established with this test. The performance of the Influenza A+B/COVID-19 Antigen Test Kit (Dry Color Latex Immunoassay) depends on antigen load and may not correlate with viral culture results performed on the same specimen.
2. Failure to follow the user manual may adversely affect test performance and or invalidate the test result.
3. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time rule out the presence of Influenza A+B/COVID-19 antigens in sample, as they may be present below the minimum detection level of the test or if the sample was collected or transported improperly.
4. As with all diagnostic tests, a confirmed diagnosis should only be made by a physician after all clinical and laboratory findings have been evaluated.
5. Positive test results do not rule out co-infections with other pathogens.
6. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after 10 days of illness are more likely to be negative compared to a RT-PCR assay.
7. Negative results from patients with symptom onset beyond ten days, should be treated as presumptive and confirmation with a molecular assay, if necessary, for patient management, may be performed.
8. Negative results do not rule out Influenza A+B and SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.
9. The product is designed for individuals by 18 or older. For individuals under the age of 18 or over the age of 65 should consider seeking adult assistance for testing.
10. There is a certain probability of false positives and false negatives.

[REFERENCES]

1.Henrickson KJ. Advances in the laboratory diagnosis of viral respiratory disease. Pediatr Infect Dis J. 2004; 23(1 Suppl):S6–S1.

2.Yu X, Lu R, Wang Z, Zhu N, Wang W, Julian D, Chris B, Lu J, Tan W. Etiology and clinical characterization of respiratory virus infections inadult patients attending an emergency department in Beijing. PLoS One. 2012; 7:e32174.

3.Betts, R.F. 1995. Influenza virus, p. 1546-1567. In G.L. Mandell, R.G. Douglas, Jr. and J.E. Bennett (ed.), Principle and practice of infectious diseases, 4th ed. Churchill Livingstone, Inc., New York, N.Y.

Operational guidelines：http://en.lansionbio.com/article/type/330_1.html

[SUPPORT SERVICES]

Information regarding available support services can also be obtained by contacting your local state and territory health department at:

Australian Capital Territory Department of Health
02 62077244 https://www.health.act.gov.au/
New South Wales Department of Health
137788 https://www.health.nsw.gov.au/
Northern Territory Department of health
1800020080 https://www.health.nt.gov.au/
Queensland Department of health
134268 https://www.health.qld.gov.au/
South Australian Department of Health
1800253787 https://www.sahealth.sa.gov.au/
Tasmanian Department of Health
1800671738 https://www.health.tas.gov.au/
Victorian Department of Health
1800675398 https://www.dhhs.vic.gov.au/
Western Australian Department of Health
1800595206 https://www.healthywa.wa.gov.au/

In the event you are experiencing problems with the test, please contact our authorized representative in Australia as above.

Additionally, you may wish to report poor performance or usability issues to the Therapeutic Goods Administration (TGA) via the Users Medical Device Incident Report, 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

[INTERPRETATION OF SYMBOLS]

IVD	For in vitro diagnostic use only
REF	Catalog number
	Manufacturer
LOT	Lot number
EC REP	European Authorized Representative
	Date of Manufacture
	Use by date
	Consult instructions for use
	Store between 4-30℃
	Contents Sufficient for < n > Tests
	Do not reuse
	Keep away from sunlight
	Fragile handle with care
	Keep dry
	Forbidden to inversion

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Version No.: 0.1

Production date and expiration see the label.

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The service is available between 9 am and 7 pm (AEST)or 9am and 8pm (AEDT),7 days a week