

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA)

Package Insert - For Self-testing

A rapid test for the qualitative detection of SARS-CoV-2 Nucleocapsid Protein, Influenza A and Influenza B nucleoproteins antigens present in nasal swab specimen. For self-testing *in vitro* diagnostic use only.

Specification

- 1 pc/Box
- 2 pcs/Box
- 5 pcs/Box
- 20 pcs/Box

English

REF

1041-14-01 1041-34-01
1041-24-01 1041-54-01



Scan this QR Code to access a video of these instructions.

KIT INSERTS



Test cassette (individually in a foil pouch with desiccant)



Lysis Buffer and Dropper



Anterior Nasal Swab (CE0197)



Instructions for use (20pcs/Box, 4*IFU)



Bio-Safety Bag

PREPARATION

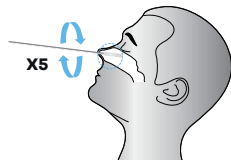
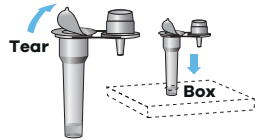
- 1 Prepare the timing tools and make sure a clean testing environment. Take out the contents and identify them correctly. Clear the nasal cavity and wash and dry the hands.
- 2 Carefully read IFU of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA).
- 3 Check the expiry date on the foil pouch. Do not use kit components after their expiration date. Open the pouch and take out the test cassette, place it on a flat surface.



This test kit should be used within 1 hour after opening the foil pouch.

ANTERIOR NASAL SECRETION TEST PROCEDURE

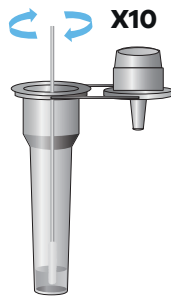
- 1 Tear the seal of the lysis buffer and place it on the test-tube rack.
- 2 Insert the swab (stick with larger absorbent tip) into a nostril (2.5 cm). Be sure to collect any nasal drainage that may be present. Those ≥18 years old can sample on their own, while children aged 5-17 years old need to be sampled and tested with the assistance of an adult. Carefully rotate the swab in a circular path against the inside of the nostril at least 5 times. Using the same swab repeat the procedure in the other nostril.
- 3 Insert the swab into the sampling tube and rotate the swab against the inner tube wall 10 times.



For specification of 1 pc/box, 2 pcs/box, 5 pcs/box, the package box can be used as test-tube rack by pushing the dotted holes on the box. For 20pcs/box please use the provided test-tube rack in the box.

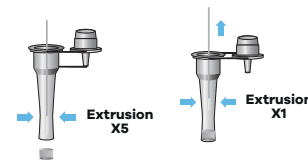
Sample should be treated with lysis buffer provided in this kit as soon as possible after collection.

If the sample cannot be processed immediately, it should be stored immediately in a dry, sterilized and strictly sealed plastic tube. It can be stored at room temperature for 1 hour, 2°C-8°C for 4 hours. Could be stored at -20°C for 1 months.



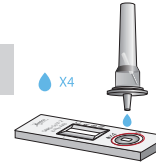
4 Squeeze the swab from the outer tube wall 5 times.

Lift the swab above the buffer solution level, squeeze the swab from the outer tube wall one time to leave the sample in the tube as much as possible.

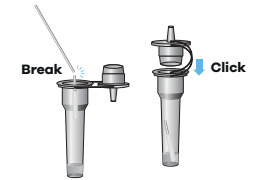


6 Add 4 drops processed sample extract into the sample well.

⚠ Open the foil pouch, then lay the test cassette on a clean flat surface



5 Break the swab and cover the tube with the dropper.



7 Read the results within 15-20 mins.

⚠ Result observed after 20 mins is invalid



Remark: Additional required but not provided equipment: Timer
Place all used materials in a Bio-safety bag, seal it tightly, and dispose of it in a household waste bin.

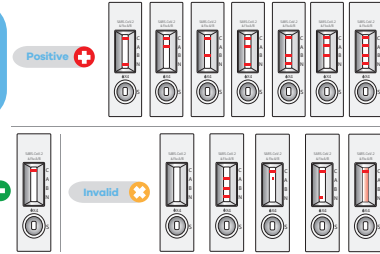
DISPLAY OF THE RESULT / EXPECTED VALUES

Positive result:

- SARS-CoV-2 Positive result: If the control line (C line) and the test line (N line) appear at the same time, it means that the SARS-CoV-2 antigen has been detected and the result is positive.
- Influenza A positive result: If both the control line (C line) and the Influenza A test line (A line) appear at the same time, it means that Influenza A antigen has been detected in the sample and the result of Influenza A is positive.
- Influenza B positive result: If both the control line (C line) and the Influenza B test line (B line) appear at the same time, it means that Influenza B antigen has been detected in the sample and the result of Influenza B is positive.

Note: The intensity of color that the test line area (N line/A line/B line) shows will vary according to the concentration of SARS-CoV-2 antigen, Influenza A antigen and Influenza B antigen. The result should be determined on whether the N line is formed or not, and is irrelevant to the color intensity. Therefore, any intensity of color in the test area (N line/A line/B line) should be considered positive.

- "C": Control Line
- "A": Influenza A Test Line
- "B": Influenza B Test Line
- "N": SARS-CoV-2 Test Line
- "S": Sample Well



face, pain or pressure in the chest, cold and clammy, or pale and mottled, skin, fainting or collapsing, being confused, difficultly waking up, little or no urine output, and coughing up blood.

- Severe COVID-19 in children is rare. Most children will have no, or only mild symptoms. If you are worried about your child's symptoms, contact your GP as soon as possible. A GP or nurse will treat your child based on their age, symptoms and past medical history. If they are showing severe symptoms, call 000 immediately.
- Most people who test positive for COVID-19 recover completely, but some people may develop long COVID. COVID-19 vaccinations, including boosters, reduce your risk of re-infection and gives the best protection against severe illness from COVID-19. After testing positive, you should wait 6 months before making a booster dose appointment.
- Individuals who have tested positive for influenza or who are unwell are advised to consult a medical practitioner for follow-up clinical care.

Negative result:

If only the control line (C line) appears and the test line (N line, A line and B line) is invisible, the sample does not contain SARS-CoV-2 and Influenza A/B antigen or the antigen concentration is lower than the limit of detection, then the result is negative.

What you need to do:

- Continue to comply with all applicable rules regarding contact with others and protective measures.
- There may be an infection even if the test is negative.
- If it is suspected, repeat the test after 1 - 3 days, as the coronavirus cannot be precisely detected in all phases of an infection.

Invalid result:

The test result is invalid if any of the following circumstances apply

1. No C line appears
2. The test line (A line / B line / N line) appears incompletely (all the way across the window)
3. A reddish background of NC film shows on the result window.

What you need to do:

- Possibly caused by incorrect test execution.
- Repeat the test with a new kit.
- If the test results remain invalid, contact the sponsor hotline for further guidance.



Please DO NOT take any decision of medical relevance without consulting your doctor/general practitioner.

Customer Support

For assistance regarding the use of the test kit and interpretation of test results, call **1800 517 206**.

The service is available from 9 am to 7 pm (AEST) 7 days per week.

INTRODUCTION

Coronavirus (CoV) belongs to the order Nidovirales under the Coronaviridae family with 4 genera: α , β , γ and δ . The α and β genera are only pathogenic to mammals, while γ and δ genera mainly cause bird infections. CoV is mainly transmitted through direct contact with secretions or through aerosols and droplets. There is also evidence supporting faecal-oral transmission.

7 kinds of human coronaviruses (HCoV) that cause human respiratory diseases have been identified so far, including: HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, SARS-CoV, MERS-CoV and SARS-CoV-2. SARS-CoV-2 is one of the most contagious viral pathogens that causes human respiratory tract infections (RTI). Currently, the patients infected by SARS-CoV-2 are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The clinical manifestations include fever, fatigue, cough and other symptoms, accompanied by dyspnoea, which can rapidly develop into life-threatening severe pneumonia, respiratory failure, acute respiratory vesicle syndrome, septic shock, multiple organ failure, and severe metabolic acid-base imbalance.

Influenza, usually called flu, is an acute respiratory infection caused by Influenza virus. It is highly contagious. It is mainly spread through coughing and sneezing. It usually breaks out in spring and winter. It is mainly divided into Influenza A and B Influenza virus. Influenza A viruses are highly variable, followed by Influenza B viruses. Therefore, Influenza A viruses are more prevalent and severe, followed by Influenza B viruses. Influenza A includes H1N1, H3N2, H5N1, H7N9, and Influenza B includes Influenza B (Victoria) and Influenza B (Yamagata).

INTENDED USE

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2, Influenza A and Influenza B virus antigen in anterior nasal swabs.

It aids in diagnosing SARS-CoV-2 infection within the first 7 days of symptom onset and influenza A/B infection within the first 4 days of symptom onset.

The test kit is designed for use as self-testing. This test kit is intended use for individuals 18 years old or above with clinical symptoms of SARS-CoV-2, Influenza A and Influenza B infection or who are suspected of SARS-CoV-2, Influenza A and Influenza B. SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) shall not be used as sole basis to diagnose or exclude SARS-CoV-2, Influenza A and Influenza B infection.

TEST PRINCIPLE

SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) uses a double antibody sandwich method to detect SARS-CoV-2 and influenza A/B by colloidal gold immunochromatography.

When the appropriate amount of test samples treated with lysis buffer is added to the sample well of the test cassette, the sample will move forward along the test strip by capillary action. If the sample contains SARS-CoV-2 and Influenza A/B virus nucleocapsid antigen, and the concentration is higher than the limit of detection, the antigen will form immune complexes with corresponding Nucleocapsid Protein antibody labeled with colloidal gold respectively, which are captured by lines N line, A line, and B line. If test sample contains SARS-CoV-2 virus, forming a red N line, indicating a positive result for SARS-CoV-2. If test sample contains Influenza A virus, forming a red A line, indicating a positive result for Influenza A. If test sample contains Influenza B virus, forming a red B line, indicating a positive result for Influenza B.

Additionally, the test strip also contains a control line (C line). The C line should be formed to indicate that the sample has been transported properly through the membrane regardless of whether sample contains antigens or not. If the C line does not appear, it indicates that the test result is invalid and the sample needs to retest.

MUTATION VIRUS DETECTION COMPATIBILITY TIPS

The SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) detects Nucleocapsid protein, NOT spike protein of SARS-CoV-2 and Influenza A/B. Influenza A (H1N1, H3N2, H5N1, H7N9) and Influenza B (Victoria/Yamagata) can be detected by the strip. And all of the following variants can be effectively detected by SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA).

WHO label	Omicron				
Pango lineage	B.1.1.529	BA.2	BA.4	BA.5	BA.2.75

CONTENTS OF THE KIT

Components Specification	Test Cassette	Anterior Nasal Swab	Lysis Buffer and Dropper	Bio-Safety Bag	Instructions for use	Test-tube Rack
For 1 Test/Box	1	1	1	1	1	Please use the package box
For 2 Test/Box	2	2	2	2	1	Please use the package box
For 5 Test/Box	5	5	5	5	1	Please use the package box
For 20 Test/Box	20	20	20	20	4	1

- Test cassette: contains the SARS-CoV-2 & Influenza A/B test strip and a plastic cassette casing.

SARS-CoV-2&Influenza A/B Antigen Combo Rapid Test Kit (LFIA) contains anti-SARS-CoV-2 Nucleocapsid Protein antibody labeled with colloidal gold, anti-Influenza A Nucleocapsid Protein antibody labeled with colloidal gold, anti-Influenza B Nucleocapsid Protein antibody labeled with colloidal gold. Another anti-SARS-CoV-2 Nucleocapsid Protein antibody, anti-Influenza A Nucleocapsid Protein antibody and anti-Influenza B Nucleocapsid Protein antibody are fixed on the N line, A line and B line respectively. The N line/A line/B line and control line (C line) are in the detection window on the nitrocellulose membrane.

WARNINGS AND PRECAUTIONS

- This test kit is used for self-testing (Layman's test).
- This test kit is used for in vitro diagnosis only.
- This test kit is intended for adults over the age of 18. It can be used by children aged 5 to 17 when supervised by an adult. It is not suitable for children under the age of five.
- Bring the kit contents to room temperature before testing.
- Proper protection should be taken during testing to avoid splashing when adding sample.

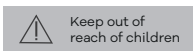
• Safety information – include warnings for the buffer (e.g., Test kit solutions should only be used as directed; do not ingest; do not dip the swab into provided solution or other liquid before inserting the swab into the nose; avoid contact with skin and eyes; keep out of the reach of children and 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)

- If influenza A/B test result is positive: There is currently a suspicion of influenza A/B infection, individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow up clinical care.

- Do not re-use the test kit.
- Do not use the test kit if the pouch is damaged, the seal is broken or the test cassette is wet or polluted.
- Do not use the test kit contents beyond the expiration date printed on the outside of the box.
- When collecting an anterior nasal swab sample, use only the Anterior Nasal Swab provided in the Kit.
- If an invalid result is produced, the user should retest with a new test.
- Do not mix with kit components from other batches.

DISPOSAL INSTRUCTIONS

Place all used materials in a Bio-safety bag, seal it tightly, and dispose of it in a household waste bin.



STORAGE INSTRUCTIONS

- The test kit should be stored away from direct sunlight at 2°C to 30°C with a shelf-life of 24 months as detailed on the primary package.
- This test kit should be used within 1 hour after opening the foil pouch.

TEST METHOD LIMITATIONS

- The accuracy of the test is dependent on the quality of the sample. Improper sampling and handling of samples can affect test results. Test results can also be affected by temperature and humidity.

- Low concentration of SARS-CoV-2, Influenza A and Influenza B antigens in the sample may cause negative results, so the possibility of infection cannot be completely ruled out.

- Some medication (e.g. high concentration of over-the-counter (OTC) or prescription medication such as nasal spray) in the collected samples may interfere with the test result. Please perform the test again if the result is in doubt.

- This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.

- The results of this test are for clinical reference only and should not be the only basis for diagnosis. Results should be used in combination with clinical observations and other testing methods.

- Recommend 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 test is less reliable when used in the condition of later phase of infection. If testing is not performed within the first 7 days symptom onset, false SARS-CoV-2 negative results may occur. If testing is not performed within the first 4 days symptom onset, false influenza negative results may occur.

- A negative result does not mean a person is not infectious or does not have influenza. If symptoms persist the person should seek medical attention.

- A negative result does not rule out infection with another type of respiratory virus.

- A positive result cannot necessarily determine whether a person is infectious.

- SARS-CoV-2 and Influenza self-testing are for use as an aid for diagnosis only and individuals with a positive result or who are unwell are advised to consult a medical practitioner for follow-up clinical care.

PRODUCT PERFORMANCE

Limit of Detection - LoD

Limit of Detection (LoD) studies determined the lowest detectable concentration of SARS-CoV-2, influenza A and Influenza B at which 100% of all (true positive) replicates test positive.

	Virus Strain	LoD (TCID50/mL)
SARS-CoV-2	BetaCoV/3502/human/2020	10 ⁶
	A/Brisbane/02/2018 (H1N1)	10 ⁴
	A/PUERTO/8/1934 (H1N1)	10 ²
	A/Kansas/14/2017 (H3N2)	10 ²
	A/Aichi/2/1968 (H3N2)	10 ²
Influenza A	A/Anhui/1/2013 (H7N9)	10 ⁴
	B/Colorado/06/2017 (Victoria)	10 ²
	B/Phuket/3073/2013 (Yamagata)	10 ²
	B/Chaoyang Beijing/12977/2017 (Yamagata)	10 ⁴

• Cross reactivity

The following commensal and pathogenic microorganisms that may be present in the nasal cavity were tested on SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) for cross reactivity and potential interference. Cross-reactivity or interference caused by these microorganisms is unlikely to occur, including Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, MERS-coronavirus, SARS-coronavirus, SARS-CoV-2, Influenza A H1N1, Influenza A H3N2, Influenza A H5N1, Influenza A H7N9, Influenza B Victoria, Influenza B Yamagata, Parainfluenza virus Type 1, Respiratory syncytial virus, Enterovirus CA16a, Adenovirus, Mycoplasma pneumoniae, Staphylococcus aureus, Staphylococcus epidermidis, Bordetella pertussis, Legionella pneumophila, Streptococcus pneumoniae, Haemophilus influenzae, Streptococcus pneumoniae, Mycobacterium tuberculosis, Candida albicans, Adenovirus 2, Adenovirus 3, Adenovirus 4, Adenovirus 5, Adenovirus 6, Adenovirus 7, Cytomegalovirus, Epstein Barr Virus, Human Parainfluenza type 3, Human Parainfluenza type 2, Measles, Human metapneumovirus, Mumps virus, Respiratory syncytial virus B, Rhinovirus, Chlamydia pneumoniae, Corynebacterium sp., Escherichia coli, Hemophilus influenzae, Lactobacillus sp., Legionella spp., Moraxella catarrhalis, Neisseria meningitidis, Neisseria sp., Pseudomonas aeruginosa, Streptococcus pyogenes, Streptococcus salivarius.

• Interfering Substances Effect

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the respiratory tract, were tested on SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA). There is no interference were found to affect the test performance: endogenous substance (Mucin, whole blood, Icteric (Bilirubin), Rheumatoid factor, Triglycerides, Hemoglobin, Anti-nuclear antibody, Pregnant, Total IgG, Total IgM, Total IgA), exogenous Substance (Mupirocin, Tamiflu (Osetamivir Phosphate), Fluticasone Propionate, Flunazalone, Zincum gluconum (i.e., Zicam), Alkalol, Phenol, Phenylephrine hydrochloride, xymetazolin hydrochloride, Cromolyn, Oxymetazoline, Galphimia glauca, Sabadilla, Albuterol, Acarbose, Osetamivir, Chlorpheniramine, Diphenhydramine, Glimperide (Sulfonylureas), Chlorothiazide, Acetyl salicylic acid, Amoxicillin, Ibuprofen, Belomethasone, Indapamide, Flunisolide, Guaiaacil glyceryl ether, Biotin, Zanamivir, Tobramycin, Sulfur, Ribavirin, Ephedrine, Benzocaine, Menthol, Budesonide, Triamcinolone, Dexamethasone, Sodium chloride with preservatives, Lopinavir, Ritonavir, Chloroquine phosphate, Ivermectin, Mometasone, Luffa operculata, Histaminum hydrochloricum, virus vaccine, Benzocaine.

• Clinical Performance

1. SARS-CoV-2 Test

The performance of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was established with 2339 anterior nasal swabs collected from patients with COVID-19 symptoms within 7 days after onset of symptoms. Two swabs were collected with the same person, an anterior nasal swab tested directly using SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) and a nasopharyngeal or oropharyngeal swab tested by the RT-PCR Test Kit. Clinical samples were evaluated to be positive or negative using RT-PCR reference method.

Test result of SARS-CoV-2

Medomics SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit	RT-PCR		
	SARS-CoV-2 Positive	Negative	Total
SARS-CoV-2 Positive	370	11	381
Negative	38	1920	1958
Total	408	1931	2339

Sensitivity: 90.69% (87.44% – 93.32%)
Specificity: 99.43% (98.98% – 99.72%)
Accuracy: 97.91% (97.24% – 98.45%)

PPV: 97.11% (94.89% – 98.55%)
NPV: 98.06% (97.35% – 98.62%)
Kappa: 0.9253

2. Influenza A Test

The performance of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was established with 1593 anterior nasal swabs collected from patients with Influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same person, an anterior nasal swab tested directly using SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) and a nasopharyngeal or oropharyngeal swab tested by the Comparison Test Kit. Clinical samples were evaluated to be positive or negative using Comparison reference method.

Test result of Influenza B

Medomics SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit	Comparison Reagents		
	Flu A Positive	Negative	Total
Flu A Positive	188	4	192
Negative	11	1390	1401
Total	199	1394	1593

Sensitivity: 94.47%, 95%CI (90.32% – 97.21%)
Specificity: 99.71%, 95%CI (99.27% – 99.92%)
Accuracy: 99.06%, 95%CI (98.45% – 99.47%)

PPV: 97.92%, 95%CI (94.75% – 99.43%)
NPV: 99.21%, 95%CI (98.60% – 99.61%)
Kappa: 0.9563

3. Influenza B Test

The performance of SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) was established with 1593 anterior nasal swabs collected from patients with Influenza symptoms within 7 days after onset of symptoms. Two swabs were collected with the same person, an anterior nasal swab tested directly using SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) and a nasopharyngeal or oropharyngeal swab tested by the Comparison Test Kit. Clinical samples were evaluated to be positive or negative using Comparison reference method.

Test result of Influenza B

Medomics SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit	Comparison Reagents		
	Flu B Positive	Negative	Total
Flu B Positive	194	3	197
Negative	13	1383	1396
Total	207	1386	1593

Sensitivity: 93.72%, 95%CI (89.50% – 96.61%)
Specificity: 99.78%, 95%CI (99.37% – 99.96%)
Accuracy: 99.00%, 95%CI (98.37% – 99.42%)

PPV: 98.48%, 95%CI (95.61% – 99.69%)
NPV: 99.07%, 95%CI (98.41% – 99.50%)
Kappa: 0.9546

• Usability study

The usability study was performed in two sites.

In summary, the whole usability study was conducted with 224 lay persons who performed the test and interpreted the result.

During the whole usability study, 100 % (224/224) of lay persons were able to use the SARS-CoV-2 & Influenza A/B Antigen Combo Rapid Test Kit (LFIA) to complete the test procedure and obtain consistent test results with professionals.

For SARS-CoV-2, The results were compared to an RT-PCR with a sensitivity of 94.59 % (35/37) and specificity of 99.11 % (222/224) .

For Influenza A, The results were compared to an RT-PCR with a sensitivity of 97.06 % (33/34) and specificity of 99.55 % (223/224)

For Influenza B, The results were compared to an RT-PCR with a sensitivity of 95.00 % (38/40) and specificity of 99.11 % (222/224).

Report Performance or Usability Issues:

Contact TGA to report poor performance or usability issues in the self-test environment.

Report an issue via the Users Medical Device Incident Report, email: iris@health.gov.au

[References]

1. LY Wang, PR Chen, G W Zheng, et al. Research progress on novel coronavirus test methods. Modern Medicine and Clinic, 2020, 35(3): 411-416.
2. K Tugba, W Ralph, L Hakko. Molecular and Immunological Diagnostic Tests of COVID-19: Current Status and Challenges. iScience, 2020, 23 (8). Doi: 10.1016/j.isci.2020.101406
3. WHO recommendations on the use of rapid testing for influenza diagnosis, World Health Organisation, July 2005.

INDEX OF SYMBOLS	
	Do not Re-use
	Do not use if package is damaged
	Catalogue Number
	In Vitro Diagnostic Medical Device
	Batch Code
	Consult instructions for use
	Sterilized using ethylene oxide
	Caution
	Use-by-date
	Contains sufficient for >= tests
	Temperature limit
	Keep Dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer