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*Revision: January 2025 (2nd version)
Prepared in September 2024 (1st version)

Read this instruction sheet carefully before use.
Please keep the instruction sheet safe so that you can read it when you need to.

Test drugs

1st Class OTC drug

SARS coronavirus antigen/
influenza virus antigen kit
for general use

アンスペクトコーワW
Inspecter Kowa W

Use of This Test

This kit is a test kit to detect novel coronavirus antigen and influenza virus antigen simultaneously. However, it is known that these viruses are different in the characteristics such as the timing when the viral load is greatest. For this reason, pay attention to the following points when using the results.

- Use this kit for self-check when cold symptoms such as pyrexia are observed. According to the results, visit a medical institution appropriately in accordance with the guidance of the local government of your region.
- Since the results may change depending on the time from the onset, record the time from onset of the symptoms to the use of this kit and tell the doctor the time together with the results of this kit when you visit a medical institution.

* Any negative result may be a false negative (the result is wrongly assessed as negative).
* Particularly, influenza is known to have a low viral load and the antigen cannot be detected in the early stage of the onset.

Mechanism of This Test (Measurement Principle)

This kit is intended to confirm the SARS coronavirus antigen and influenza virus antigen existing in nasal swab shown as a line on the kit, by binding the antibodies against each antigen on the test kit.

Precautions for Use

What Not To Do

You cannot make a diagnosis of disease by yourself based on the test results (please follow the "Use of This Test" above).

Consultation

Consult a doctor or pharmacist if there is anything that is difficult to understand in this instruction sheet.

Precautions Concerning Disposal

Dispose of this kit and cotton swab used for sampling as household waste according to your local waste management guidelines.
A used cotton swab, etc. may be infectious and it should be handled with great care when disposed of. Be careful to prevent the used kit (including a cotton swab and tube, etc.) from scattering by putting it in a garbage bag, tying the bag tightly and sealing the bag, and using another bag to wrap the garbage bag double if the waste touches the outer surface of the garbage bag or the garbage bag is torn.

Intended Use

Detection of SARS-CoV-2 antigen, influenza A virus antigen, and influenza B virus antigen in nasal swab
(Supplemental test for determination of suspected SARS-CoV-2 infection or suspected influenza virus infection)

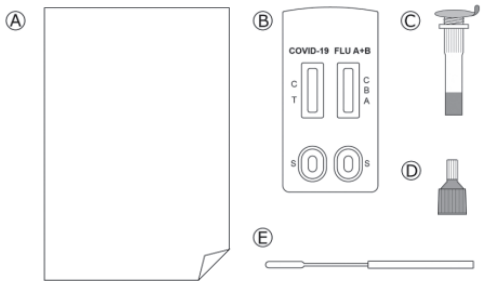
Instructions for Use

●Preparation for the test

＜Check of contents of the kit＞

Take the contents out of the box and check whether all the necessary components are included.

Ⓐ Package insert (this document)
Ⓑ Test cassette (in aluminum pouch) ... 1 piece
Ⓒ Extraction buffer (in tube) ... 1 piece
Ⓓ Dropping Tip ... 1 piece
Ⓔ Sterilized cotton swab (for nasal cavity) ... 1 piece



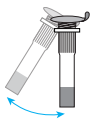
＜Preparation before sampling ＞

① Return the test cassette (kept in the aluminum pouch) and extraction buffer to the temperature of 15 to 30 degrees C. before use if they have been stored in a refrigerator, etc.
Use the test cassette within 1 hour after opening. Do not use if the aluminum pouch is damaged.

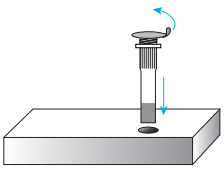
② Prepare a clock or a timer before testing.

③ Cut a round cut line at the bottom right of the surface.

④ Gently shake the tube containing the extraction buffer to let the extraction buffer attached to the side of the tube drop.



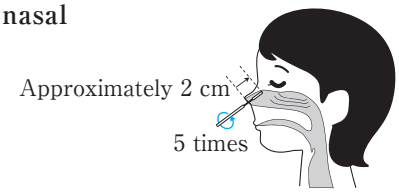
⑤ Move the tube away from your face as far as possible, and peel off the seal with care to prevent the extraction buffer from splashing and stand the tube.



●How to test

＜Sampling (self-collection of nasal swab)＞

① Insert the sterilized cotton swab provided with the kit (for nasal cavity) approximately 2 cm along the nasal cavity.

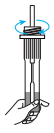


② Rotate the cotton swab about 5 times along the inner wall of the nose, and then allow to stand for 5 seconds, and pull it out.

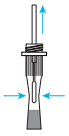
③ Make sure that the swab is sufficiently moist.

＜Sample preparation＞

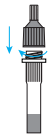
① Put the ball portion of the cotton swab used to collect the sample into the tube containing the extraction buffer quickly. Hold the tube and stir for 10 seconds while pinching the ball portion of the cotton swab from outside the tube to extract the sample.



② After squeezing the liquid by pinching the tube against the cotton swab strongly, withdraw the swab straight along the tube and discard the cotton swab.



③ Securely attach the dropping tip to the tube.

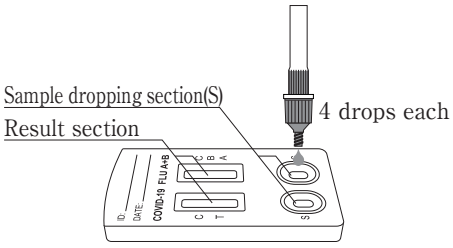


＜Dropping of sample＞

① Take the test cassette out of the aluminum pouch immediately before use and place it horizontally with the result window side up.
Note) When opening, do not touch the sample dropping section or the result window of the test cassette.

② Uncap the dropping tip of the tube.

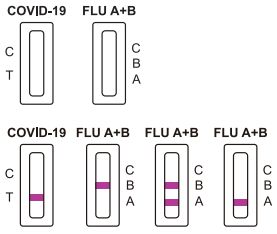
③ Slowly turn the tube upside down and gently press the side of the tube to drop 4 drops of the sample extraction buffer each into the sample dropping section (S) of the test cassette.
There are 2 sample dropping sections: COVID-19 Test (left) and FLU A+B Test (right). Drop the 4 drops of the sample solution to each of the 2 sample dropping sections. Drop the sample solution vertically while preventing the tip of the tube from touching the sample dropping section.



④ Allow to stand for 15 minutes for determination.
Note) Do not move or touch during the test.

●How to determine

After allowing to stand for 15 minutes, determine the result section of the test kit as follows.

Determination method	Results
 **SARS-CoV-2 antigen Positive** When a reddish purple line is observed in the result section T and result section C of COVID-19 Test.	The novel coronavirus antigen was detected. Check the latest information, etc. provided by the local government in your region and visit medical institutions, etc. appropriately.
 **Influenza A virus Positive** When a reddish purple line is observed in the result section A and result section C of FLU A+B Test and no line is observed in the result section B.	Influenza A virus antigen was detected. Check the latest information, etc. provided by the local government in your region and visit medical institutions, etc. appropriately.
 **Influenza B virus Positive** When a reddish purple line is observed in the result section B and result section C of FLU A+B Test and no line is observed in the result section A.	Influenza B virus antigen was detected. Check the latest information, etc. provided by the local government in your region and visit medical institutions, etc. appropriately.
 **Negative** When a reddish purple line is observed in the result section C and no line is observed in the result section T of COVID-19 Test.  When a reddish purple line is observed in the result section C and no line is observed in the result section A or result section B of FLU A+B Test.	Neither novel coronavirus antigen nor influenza A or B virus antigen was detected. Considering the possibility of false negative results (the result is wrongly assessed as negative), visit a medical institution, etc. appropriately.
 **Undeterminable (retest)** When no line is observed in the result sections C of COVID-19 Test and FLU A+B Test.	Even if lines are observed in the result section T, result section A, and result section B, the test result is invalid because no line is observed in the result section C. Perform the test again using a new test kit.

Pay attention to the following points when using this kit.

＜Precautions concerning sampling＞

- ●Always use a clean cotton swab (the cotton swab provided with the kit).
- ●Put the sample in the provided tube (extraction buffer) immediately after the collection and perform the test immediately.
- ●If the sampling method and site are different from the instructions, correct results may not be obtained.
- ●The determination may be difficult if the amount of sample collected is excessive, or the viscosity of the sample is high, or a solid substance is contained in the sample, because such sample may make the background color left in the result section or make the coloration of the line in the result section weak.

＜Precautions concerning test procedures＞

●If the extraction buffer accidentally gets into the eyes or mouth or adheres to the skin, take emergency measures such as washing thoroughly with water, and get medical attention as needed.
●Do not reuse the test cassettes or the tube containing extraction buffer.
●After dropping the extraction buffer, do not lift or move the test cassette until the test is completed.

＜Precautions concerning determination＞

●If the determination is made after the specified time, the results displayed on the test kit may change. Make sure to make determination at the specified time. Considering the case where you tell a medical institution, etc. the results obtained by this test kit, it is recommended to take photo of the result section together with the note on which “time of onset of the symptoms" and "time of use of this kit" are recorded.

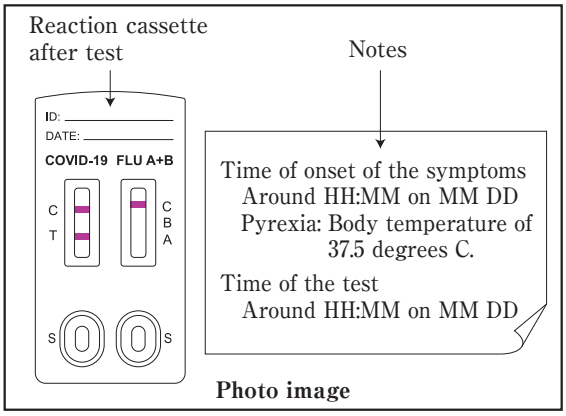


Photo image

●If the results displayed on the test kit are not clear, making determination difficult, visit a medical institution, etc. appropriately as in the case of positive results.
●No line in the result section T indicates the result that SARS-CoV-2 antigen was not detected; however, the following possibility cannot be ruled out: the sample was not successfully collected, or the level of the antigen was lower than the detection sensitivity of this kit even if SARS-CoV-2 was present in the sample.
●No line in the result section A or the result section B indicates the result that influenza virus antigen was not detected; however, the following possibility cannot be ruled out: the sample was not successfully collected, or the level of the antigen was lower than the detection sensitivity of this kit even if influenza virus was present in the sample.
●Reddish purple lines may be observed in the result sections A, B, and C, indicating that both influenza A and B virus antigens are positive. The incidence of superinfection with influenza A and B viruses is very rare. In addition, if the lines in the result sections A and B are unclear, false-positive results may be considered, and therefore perform test again or visit a medical institution, etc.
●A part of the line in the result section may be missing although the frequency is low. A slightly missing line does not affect the results. The test result is valid if a line is observed. An irregular streak line may appear temporarily during the reaction. If it is difficult to identify the line in the result section, perform the test again.
●For the line in the result section C, the color tone or shade may change depending on the amount of antigen in the sample or sample-derived components, but the test result is valid if a color can be identified.
* ●A positive result may be obtained with this kit during a certain period after vaccination with an intranasal attenuated live influenza vaccine because of vaccine-derived influenza virus.

Contents of the Kit and the Ingredients

[Contents] 1-test kit for once
In 1 test
Test cassette
(Ingredient) Mouse anti-SARS-CoV-2 antigen monoclonal antibody
Colloidal gold conjugated mouse anti-SARS-CoV-2 antigen monoclonal antibody
Mouse anti-influenza virus A antigen monoclonal antibody
Mouse anti-influenza virus B antigen monoclonal antibody
Colloidal gold conjugated mouse anti-influenza virus A antigen monoclonal antibody
Colloidal gold conjugated mouse anti-influenza virus B antigen monoclonal antibody
Extraction buffer (in tube)
Dropping Tip
Sterilized cotton swab (for nasal cavity)

Precautions for Storage and Handling

① Keep out of reach of children.
② Store at 2 to 30 degrees C. away from direct sunlight, high temperature, and high humidity.
③ The reaction temperature range of this kit is 15 to 30 degrees C. Be careful not to deviate from the range when testing in a cold place or near a heater.
④ To maintain the quality, do not replace the product to other containers.
⑤ Open immediately before use.
⑥ Do not use the product after the expiration date.
⑦ Do not directly touch the sample dropping section and the result window of the test cassette with hands, etc.

Storage Period/Shelf Life

Store at 2 to 30 degrees C. for 24 months (The expiration date is indicated on the outer box.)

Packaging Unit

For single use

Distributor: Kowa Company, Ltd. 3-4-14, Nihonbashi-Honcho, Chuuo-ku, Tokyo
Marketing Authorization Holder: NICHIREI BIOSCIENCES INC. 6-19-20, Tsukiji, Chuo-ku, Tokyo

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