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[Prepared in September 2022]

OTC Reagent

1st class OTC drug

Read this instruction manual carefully before use.
Keep this instruction manual available for reference when needed.

SARS Coronavirus Antigen Kit for OTC Reagent

アンスペクトユーワ SARS-CoV-2 (一般用) Inspector KOWA SARS-CoV-2 (OTC drug)

Use of SARS-CoV-2 antigen testing

Use the kit for self-check when feeling unwell, etc. If you test positive, visit a medical provider.

There is a chance of false negative result (a chance that this test will give you a negative result when you have COVID-19). If you test negative, but have symptoms, visit a medical provider. Even if you have no symptoms, please continue to practice measures to prevent infection from COVID-19, including wearing a face mask when going out and hand sanitizing.

* If there is any local guidance on how to contact medical providers, visit a medical provider or follow the necessary steps in accordance with the guidance.

* See the latest information from the Ministry of Health, Labour and Welfare for information on how to use the kit for a person who was determined to be a close contact.

Mechanism of determining presence or absence of SARS-CoV-2 antigens (measurement principle)

SARS-CoV-2 antigens contained in saliva bind to anti-SARS-CoV-2 antibodies on the test cassette, resulting in a visible line, indicating a positive result.

⚠️ Precautions for use



You are not allowed to ...

You are not allowed to diagnose your condition based on the test result (follow the information in "Use of SARS-CoV-2 antigen testing").



Please consult ...

If there is any question or ambiguity in this manual, consult with a physician or pharmacist.

Disposal precautions

Dispose of the kit, swabs and other materials used for specimen collection as household waste in accordance with the local regulations on waste disposal procedures.

Used swabs, etc. may be infectious. Dispose of these materials with caution. Put used kits (including swabs and tubes) in a trash bag, tie the bag tightly closed. If the used materials come in contact with the exterior of the bag, or the bag is torn, take precautions such as putting the bag in another trash bag to prevent the content from scattering.

Intended use

To detect SARS-CoV-2 antigens in saliva (decision aid to identify a patient with suspected SARS-CoV-2 infection)

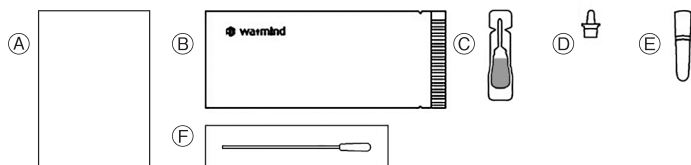
How to use the kit

● Preparation of test

<Check the content of the kit>

Take out the content of the kit and check to make sure that all components are included.

- (A) Package insert (this instruction manual)
(B) 1 test cassette (in aluminum bag)
(C) 1 antigen extraction buffer (D) 1 filter cap (E) 1 tube
(F) 1 cotton swab for saliva collection



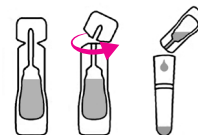
<Preparation before specimen collection>

- Do not eat, drink, smoke, brush teeth, or rinse mouth for at least 30 minutes before specimen collection. If saliva is not collected as instructed, the result may not be accurate.
- Have a clock or timer ready.
- Perform a test at a temperature of 15°C-30°C with humidity ≤70%.

- ① Cut out a circle along the line in the bottom right of the top surface of the kit box and stand the tube in the hole.



- ② Open the container of antigen extraction buffer by twisting the tip off. Pour all of the buffer into the tube standing on the kit box. Be careful not to spill.

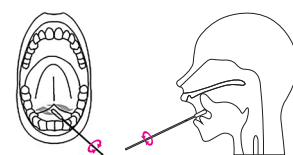


● How to perform a test

<Specimen collection (self-collection of saliva)>

When removing the swab from the package, be careful not to touch the soft tip of the swab.

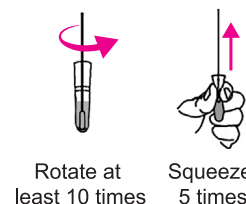
Take out the cotton swab from the package. Place the tip of the tongue against the upper jaw and collect saliva in the lower jaw. Place the swab under the tongue, immersing it in the accumulated saliva, for at least 40 seconds, and then rotate the swab at least 5 times to collect saliva sample.



<Preparation of sample>

- ① Hold the tube and place the swab with collected saliva into the tube.

- ② Immerse the swab tip completely in the buffer, and allow it to rotate at least 10 times (keeping the tip immersed in buffer) pressing the swab against the wall of the tube. Squeeze the swab 5 times from the outside of the tube by pinching with fingers and pull out the swab so that the solution remains as much as possible in the tube.



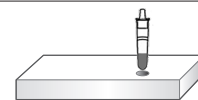
Caution: Do not put the swab in the mouth after dipping in the tube.

Caution: Do not let bubbles form in the extraction buffer.

- ③ Discard the swab and cap the tube tightly with a filter cap. Mix well by rotating the tube 5 to 6 times and patting the lower part of the tube.



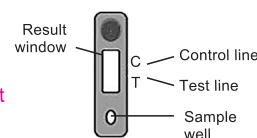
- ④ Place the tube upright on the hole of the box again.



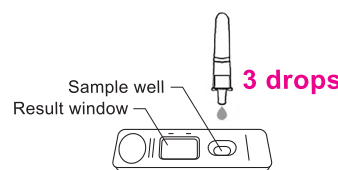
<Adding sample>

- ① Remove the test cassette from the aluminum bag and place it on a flat, clean and dry surface.

Caution: Open the package of the test cassette immediately before use. Do not touch the sample well or result window of the test cassette after opening.



- ② Squeeze 3 drops of the sample solution to the oval sample well on the test cassette.



- ③ Wait 15 minutes.

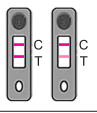
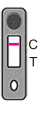
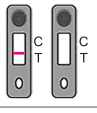
Caution: Do not move or touch the test cassette.

Caution: Results read after 20 minutes may be inaccurate.



● Result interpretation

After letting stand for 15 minutes, read the result by 20 minutes by determining whether a line is present in the result window as shown below:

Result	Interpretation
Positive  Both a control line (C) and a test line (T) are present	SARS-CoV-2 antigens have been detected. Check the latest information of the local health authority and visit a medical provider or follow the necessary step.
Negative  The control line (C) appears and no line at the test line (T)	SARS-CoV-2 antigens were not detected. There is a chance of false negative result (a chance that this test will give you a negative result when you have COVID-19). If you still have symptoms, visit a medical provider or follow the necessary step, in a manner equivalent to that required for a person who tested positive. Even if you tested negative, continue to practice measures to prevent infection from COVID-19.
Invalid (Retest)  No line appears at the control line (C)	Although a line appears at the test line (T), no control line (C) is present, indicating that the result is invalid. Perform a test again using a new test kit.

Follow the precautions below when using the kit

<Precautions for specimen collection>

- You must use a clean swab (included in the kit).
- After collection, place the specimen immediately in a tube (antigen extraction buffer; included in the kit), and perform a test promptly.
- If a specimen is collected from a different area or by a different method from those in the instruction, the result may be inaccurate.

<Precautions for testing procedure>

- If the solution makes contact with the skin, or accidentally gets in the eye or the mouth when using the kit, wash thoroughly with water. Seek medical attention as necessary.
- Do not mix or combine this kit with a different kit.

<Precautions on interpretation>

- The results indicated on the test cassette may change after the specified time period. You must interpret the result within the specified period.
- If the result shown on the test cassette is unclear, and it is difficult to interpret, visit a medical provider or follow the necessary steps, in a manner equivalent to that required for a person who tested positive.
- A person who is infected with severe acute respiratory syndrome coronavirus (SARS-CoV) may test positive (cross reaction).

Kit contents and ingredients

[Contents] Single use test kit: 1 test

- 1 test cassette

[Ingredients]

- Mouse anti-SARS-CoV-2 monoclonal antibodies
- Mouse anti-SARS-CoV-2 monoclonal antibodies labelled with colloidal gold
- 1 antigen extraction buffer
- 1 cotton swab for saliva collection

Precautions for storage and handling

- ① Keep away from the reach of children.
- ② Store at 2°C-30°C, protected from direct sunlight, high temperature, and moisture.
- ③ The reaction temperature for this kit ranges from 15°C-30°C. Make sure that the reaction temperature is within the range, when tested in a cold place, near a heater, or other testing conditions.
- ④ Tests should be performed in a room with humidity not greater than 70%. Be careful when performing a test in an area with higher humidity.
- ⑤ To maintain the quality of the kit, do not transfer the content of this kit to another container.
- ⑥ Open the package immediately before use.
- ⑦ Test kits should not be used past the expiration date.
- ⑧ Do not touch the sample well or the result window with your hands or other objects.

Storage period/shelf life

18 months (see the expiration date on the outer box)

Package unit

Single use

Approval condition

To conduct a post-marketing stability study under practical storage conditions.



Supplier:

興和株式会社

4-14 Nihonbashi Honcho 3-chome, Chuo-ku,
Tokyo 103-8433

Manufacturer: Medical & Biological Laboratories Co., Ltd.

1063-103 Terasawaoka, Ina-shi, Nagano
396-0002 Japan