



Test drugs

Category I Medicines

General-purpose SARS Coronavirus Antigen Test Kit: "Panbio™ COVID-19 Antigen Rapid Test (for General Use)"

What Is a COVID-19 Antigen Test? (Test Principle)

Panbio COVID-19 Antigen Rapid Test (for General Use) is an immunochromatographic test agent that detects novel coronavirus (COVID-19) antigens present in nasal swab solution, used for self-testing when an individual becomes concerned about their health.

Kit Contents and Composition

Test Device (Reactive Ingredient(s))

Anti-SARS-CoV-2 murine monoclonal antibodies

Anti-SARS-CoV-2 human monoclonal antibodies conjugated with colloidal gold particles

Extraction Solution

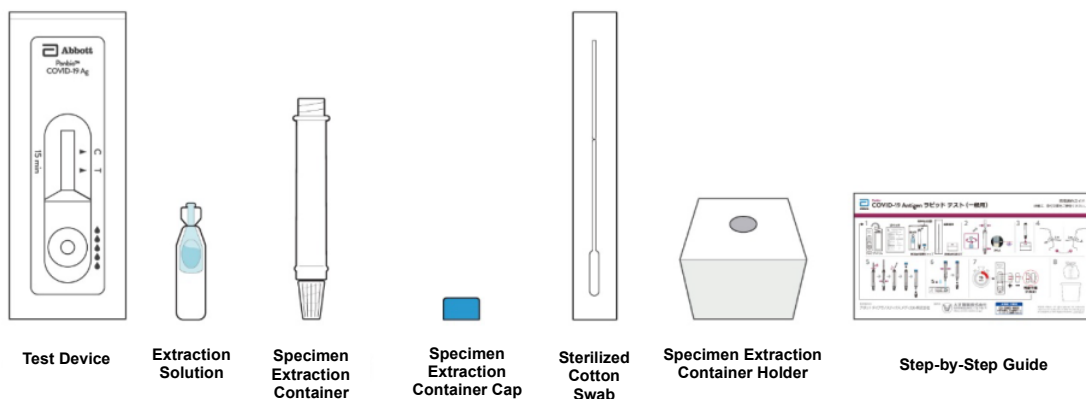
Specimen Extraction Container

Specimen Extraction Container Cap

Sterilized Cotton Swab

Specimen Extraction Container Holder (Note: The shape of the holder for a single test is different from the holder for four tests)

Step-by-Step Guide



How to Use the Test Agent

- See here for how to use the test agent (animation).



Preparing for the Test

①

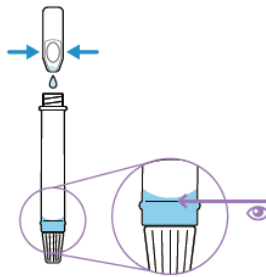


Twist and snap off the top of the extraction solution ampule.



- There is a possibility that the extraction solution may splash out when you twist and snap off the top of the extraction solution ampule, so please hold the lower end of the ampule, not the part where the solution is pooled, and twist with the nozzle facing upward.

②

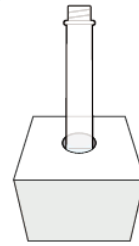


Keep the extraction solution ampule upright and pour 300 μ L of the extraction solution into the specimen extraction container, until it reaches the upper limit line (300 μ L).



- Do not dispense all of the extraction solution.
- If there is too much or too little of the extract solution, you may not obtain accurate results.

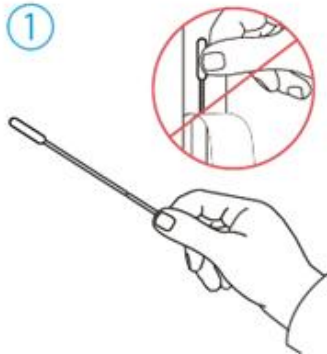
③



Place the specimen extraction container that has been filled with the extraction solution into the specimen extraction container holder.

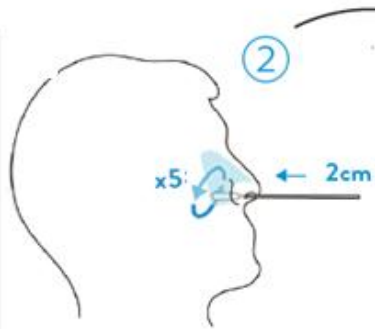
Collecting the Specimen (Collecting Your Own Nasal Swab Solution)

①



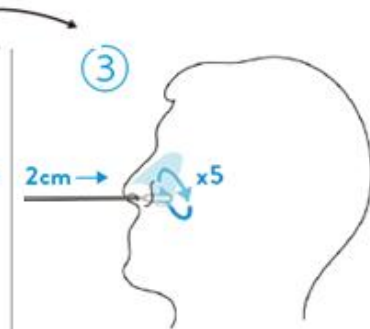
Take a sterilized cotton swab out of the bag without touching the tip of the swab (the cotton bud area).

②



Slowly insert the sterilized cotton swab about 2 cm into one nostril, as shown in the diagram. Make five rotations of the sterilized cotton swab along the inside walls of the nostril.

③

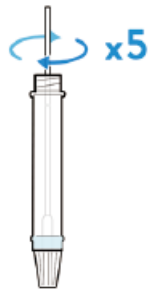


Slowly remove the swab and, using the same swab, repeat the specimen collection with the other nostril. Please check that the swab is sufficiently moist after specimen collection is done.

Preparing the Specimen

Please be prompt in preparing the specimen after you have collected it.

①



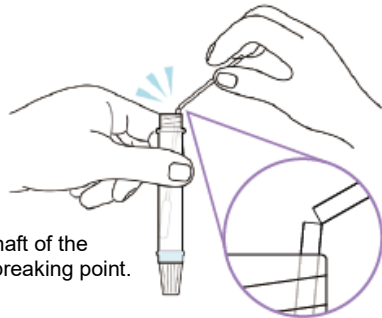
Soak the tip of the swab used for specimen collection in the extraction solution and, while pressing the tip against the sides of the tube, rotate the swab at least 5 times.

②



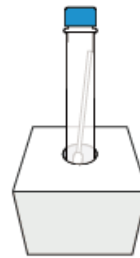
Then, pinch the cotton tip through the outside of the specimen extraction container and squeeze out the specimen.

③



Break the shaft of the swab at its breaking point.

④



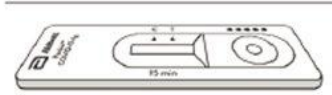
Close the cap of the specimen extraction container firmly and place the container in the specimen extraction container holder.



- **Make sure to close the cap firmly.**

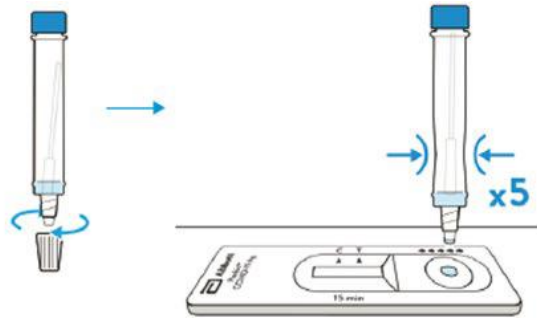
Dispensing the Specimen

①



Take out a test device from the aluminum pack and place it on a flat surface.

②



Remove the cap of the dropper nozzle at the bottom of the specimen extraction container. Squeeze the container to dispense 5 droplets of the specimen solution vertically into the



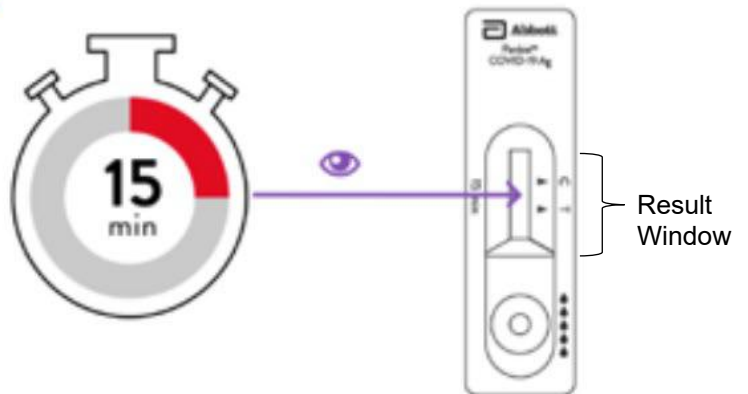
- Do not move the test device until the reaction has completed.
- Bubbles in the specimen extraction container may cause an inaccurate result. If an appropriate amount of the solution cannot be dispensed, the nozzle may be clogged. Please gently shake the specimen extraction container to clear any blockages.

③



Please close the dropper nozzle cap and then dispose of the used specimen extraction container.

④

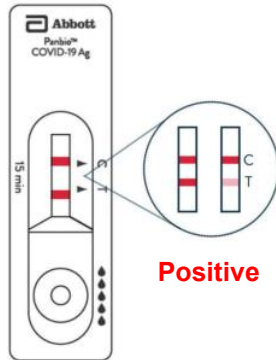


After 15 minutes, read the result window of the test device. Determine your result based on the presence or absence of lines. Do not determine your result from a test device after 20 minutes have passed since the reaction.

Determining Your Result

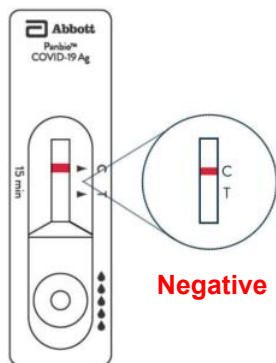
Positive

When lines appear in the test line area (T) and the control line area (C)



Negative

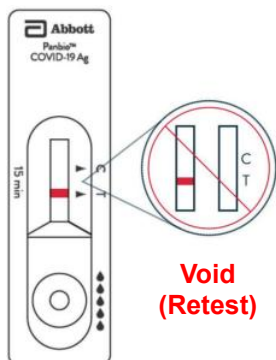
When a line appears in the control line area (C) only and no line appears in the test line area (T)



Keep in mind that false negative results (the test wrongly determining a negative result) are possible. If you are experiencing symptoms, please seek appropriate medical advice as you would in the case of a positive result.

Void (Retest)

A line fails to appear in the control line area (C)



Considerations Regarding Results

- Please make sure to read the result at the specified time. The result displayed on the test device may change if it is left to stand for longer than the specified amount of time.
- If the result displayed on the test device is unclear and/or difficult to determine, please seek appropriate medical advice as you would in the case of a positive result.
- If a line appears, no matter how faint, read it as a line being present.
- If you have been infected with severe acute respiratory syndrome coronavirus (SARS-CoV), this product may show a positive result (cross-reaction).
- Substances that could be present in the specimen or nostrils (interfering substances and interfering agents) have been evaluated and confirmed to have no effects on the test results.

Precautions for Use

What you must not do:

It is not possible to diagnose yourself with the disease from the test results. If you receive a positive result, please seek appropriate medical advice.

Consultation:

If you find any of the contents of these instructions unclear, please consult your physician or pharmacist.

Precautions for disposal:

Dispose of this kit and the cotton swabs used for collecting specimens as household waste in accordance with the disposal method specified by your local government.

Swabs and other test contents may become infectious after use, so please handle with care at the time of disposal. To avoid scattering the used kit (including cotton swabs and specimen extraction containers), place it in a disposal bag and tightly tie and seal the bag. Place it in a double disposal bag if the disposed kit touches the outer surface of the bag or if the bag is torn.

Precautions for Storage and Handling

- ① Please store this product outside of the reach of children.
- ② Please avoid exposing the test kit to direct sunlight, high temperatures or humidity, and store it at 2 to 30°C. Do not freeze.
- ③ To preserve the quality of this kit, please do not transfer it to other containers.
- ④ Do not re-use the test devices.
- ⑤ Please open the packaging immediately prior to use.
- ⑥ Do not use the test kit beyond its expiration date.
- ⑦ Do not touch the specimen well or the result window directly by hand.

Disclaimers for Multilingual Product Information

- This product is a pharmaceutical product approved under Japan's Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices for the purpose of sale and use within in Japan.
- The non-Japanese language multilingual product information is a translation of the Japanese language version of this documentation, which lists information compiled from the Japanese language versions of the package insert and other such documentation for this product, and is provided for reference purposes only. Its contents and the product itself are not guaranteed to conform to laws and regulations in countries other than Japan.
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