# **An Operating Guide for Inspecter Kowa SARS-CoV-2**





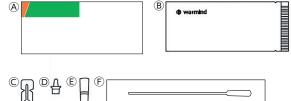
## Please carefully read this operating guide before use.

#### <Pre><Pre>cautions for use>

- Refrain from eating and drinking, smoking, brushing your teeth, and washing your mouth from 30 minutes before the saliva specimen is collected.
- Take necessary infection control measures when collecting and handling the specimen.
- If the solution comes into contact with the skin or gets into the eyes or mouth, rinse thoroughly with water.
- Prepare a plastic bag for disposal in advance, place the kit to be disposed of in the bag, seal it tightly, and dispose of it according to local regulations.
- The kit must be protected from direct sunlight and high temperatures and humidity and stored at 2 to 30°C. Maintain room temperature (15 to 30°C) before use.
- Check the expiry date indicated on the kit box. Do not use expired kits.

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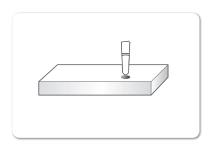


Caution: Inspecter Kowa SARS-CoV-2 does not contain a sterile container for saliva collection.

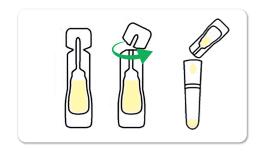
Caution: The content and appearance of the kit may be changed without notice.

## ① Preparations before collecting a specimen

- 1. Take out the content from the kit box and check that all components (6 pieces, A to F) are present.
- Cut off the circular tear-off line on the bottom right of the surface of the kit box and allow the tube to stand upright in the hole.



Open the solution container by screwing the tip of it and place the solution in the tube on the kit box without spilling any solution.

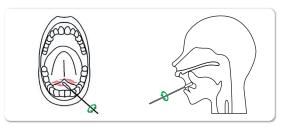


## ② Sampling of a saliva specimen

Collect the saliva by any of following methods.

## [Collection method 1] Direct collection of saliva by holding the swab in the mouth

Take out the swab from the bag. Collect saliva in the lower jaw by having the tongue tip touch the upper jaw. Immerse the swab in the saliva collected in the lower jaw for at least 40 seconds and sample the saliva by rotating the swab at least 5 times.



## [Collection method 2] Use of a sterile container for saliva collection

Collect about 1 to 2 mL of saliva in the sterile container or equivalent for saliva collection. Take out the swab from the bag, immerse it in the collected saliva in the container and allow the saliva to permeate the swab entirely while rotating it.



Caution: The kit does not contain a sterile container for saliva collection. Prepare any sterile container or equivalent separately.

Caution: A saliva specimen containing a large amount of highly viscous components, such as sputum, may lead to a misreading of the result, so store the naturally and gradually running saliva in a sterile container or equivalent.

Caution: When taking out the swab from the bag in both collection method 1 and 2, ensure that you do not touch the swab ball.

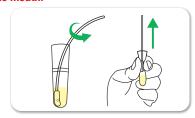


## **3Method of specimen extraction**

- 1. Hold the tube and place the swab that has been used for sampling the saliva in the tube.
- Immerse the swab in the solution thoroughly and rotate it at least 10 times (in the solution) by rubbing the side of the tube with it.

**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.

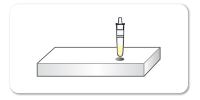
Caution: Once placed in the tube, the swab must not be placed in the mouth.



3. Seal the tube with the dripper and mix well by rotating 5 or 6 times and gently flipping the bottom of the tube with the fingers.



4. Allow the tube to stand upright again in the hole of the kit box.



## **4**Testing procedure

1. Take out the test card from the pouch and place it on a clean dry flat surface.

Caution: Open the test card immediately before use.

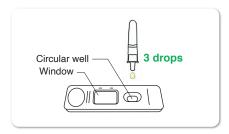
After opening, do not touch the circular well or the window of the test card.

2.3 drops of the specimen are added from the tube to the circular well of the test card.

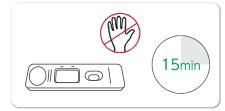
Caution: Do not use 4 or more drops of the specimen.

3. Leave the specimen for 15 minutes.

Caution: Allow the test card to stand at room temperature (15 to 30°C) without moving or touching it.







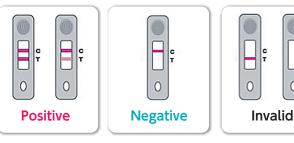
Place the kit to be disposed of in the plastic bag, seal it tightly, and dispose of it according to local regulations. Wash the hands thoroughly with running water and soap before using the kit or after disposing of waste. If the kit to be disposed of was in contact with the outside surface of the bag or the bag is broken, double the plastic bags.

Reference: The Ministry of the Environment website (materials on countermeasures to waste related to COVID-19) "How to Dispose of Household Garbage: For Infection Prevention and Control Measures to the Novel Coronavirus" https://www.env.go.ip/recycle/waste/sp\_contr/infection/coronakoho.html

## **5**Method of reading the test result

After allowing to stand for 15 minutes, by up to 20 minutes, determine the result by checking for the presence of any line in the window (refer to the figure below).

Caution: After 20 minutes, a misread result is likely.



## If the result is [positive]:

If the result is positive, please contact the primary care physician, a local medical institution near to you, or a COVID-19 consultation center for the area. As a result, a retest may be needed at a medical institution or equivalent.

## If the result is [negative]:

A negative result from this test does not exclude the possibility of SARS-CoV-2 infection because of the nature of the qualitative antigen testing. The result may also be a false-negative (wrongly read as negative), so if you have any symptoms, please visit a medical institution. Even if you have no symptoms, please continuously try to prevent infection.

## If the result is [invalid]:

If no line appears in the window [C] more than 20 minutes after inserting the specimen, the result is invalid. Please retest with a new kit.

Manufacture: Medical & Biological Laboratories Co., Ltd.

Supplier: Kowa Company, Ltd.