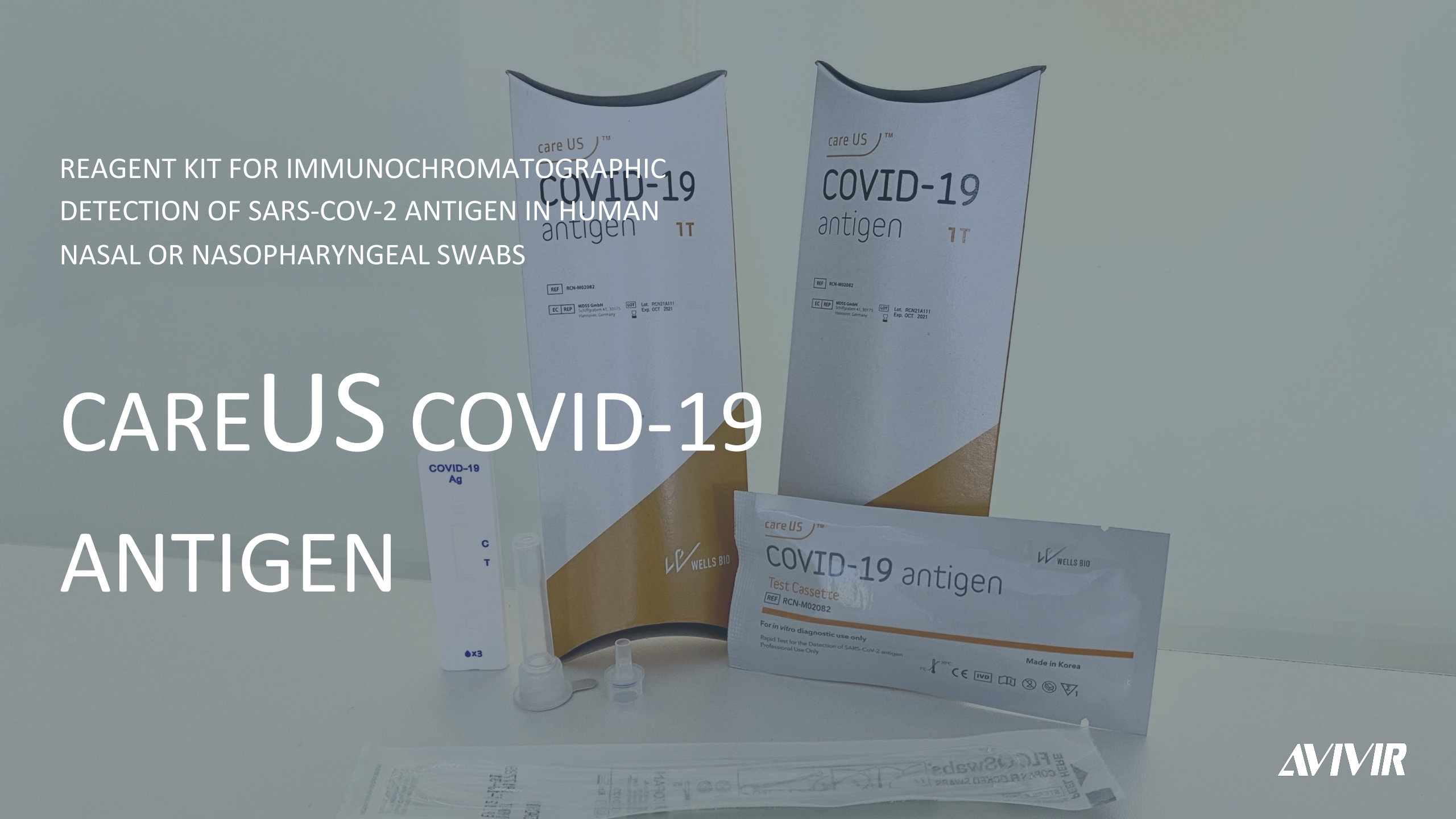
REAGENT KIT FOR IMMUNOCHROMATOGRAPHIC DETECTION OF SARS-COV-2 ANTIGEN IN HUMAN NASAL OR NASOPHARYNGEAL SWABS

CAREUS COVID-19 ANTIGEN



AVIVIR

MEDICAL DEVICE DESIGNATION

Designed for the qualitative detection of SARS-CoV-2 antigen in nasal and nasopharyngeal swabs.

The kit is only suitable for *in vitro* use.

INDICATIONS

For the qualitative detection of the SARS-CoV-2
antigen in nasopharyngeal swab specimens from individuals with respiratory disease signs and symptoms who are suspected of COVID-19.

CONTRAINDICATIONS

1. Expired test.
2. Damaged package.
3. Inadequate product storage and transportation.
4. There are no other contraindications unless the specimen cannot be taken for medical reasons.

REAGENT KIT FEATURES

The careUS COVID-19 Antigen Reagent Kit is designed for the qualitative and rapid detection of the SARS-CoV-19 antigen in nasopharyngeal swab.

Easy-to-use test strips. Testing time 5 minutes.

CLINICAL AND LABORATORY TESTING

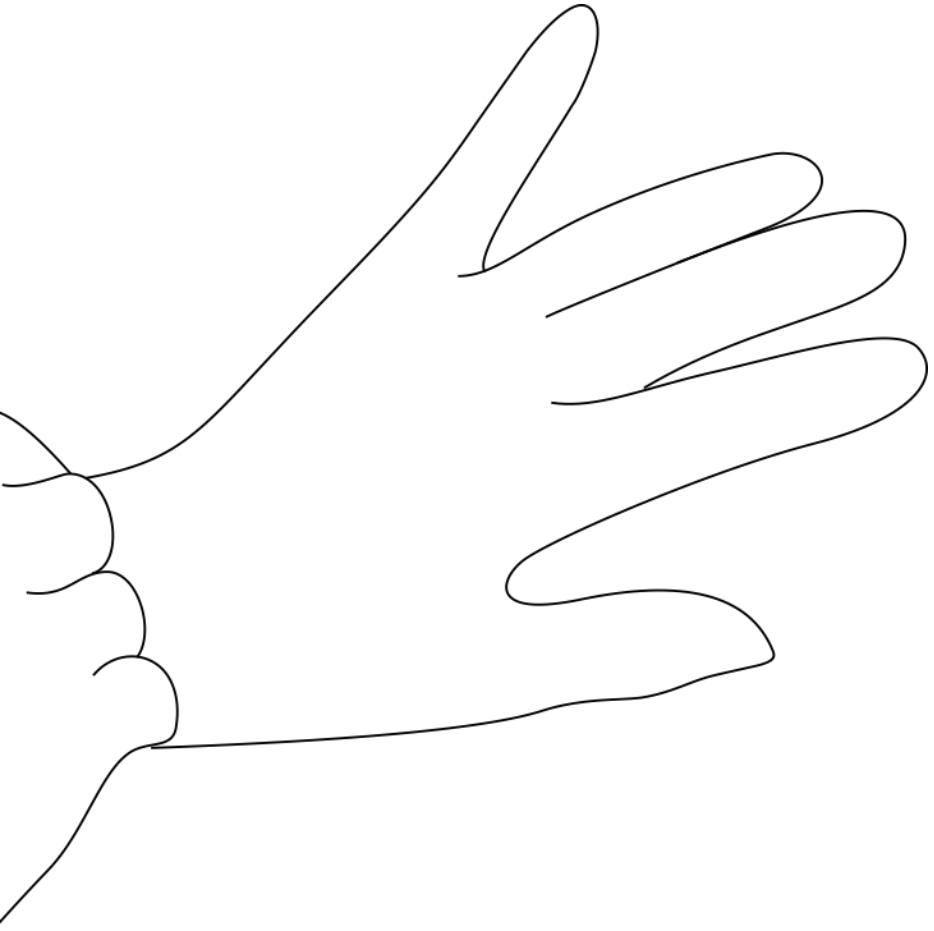
KIT CONTENTS

The product is a reagent kit containing:

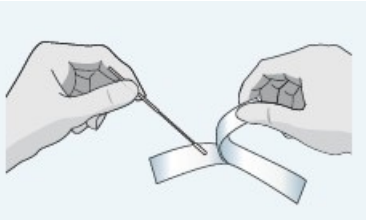
- Test cassette (single-packed) — 1 pc.
- A test tube with a buffer for biological sample diluting — 1 pc.
- Dropper cap — 1 pc.
- Flexible flocked swab for biomaterial collection — 1 pc.
- Instructions for use — 1 pc.

The following materials are not provided: protective gloves, safety goggles.

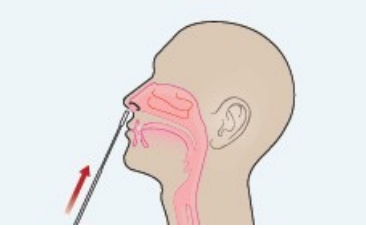
NASAL SWAB COLLECTION



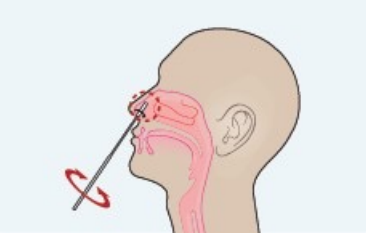
1. Remove a nasopharyngeal swab from package.



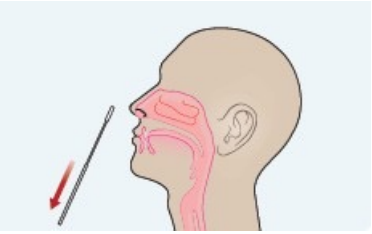
2. Insert the nasopharyngeal swab into one of the patient’s nostrils up to 2.5 cm from the edge of the nostril.



3. Slowly rotate the swab 5 times around its axis over the surface of the nostril. Repeat this process in the other nostril using the same swab.

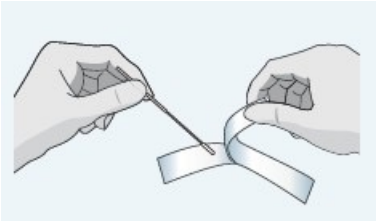


4. Remove the swab from the nostril.

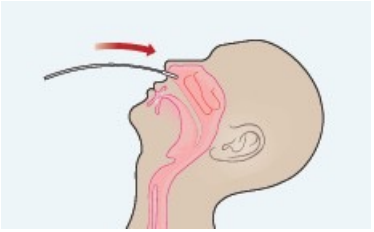


NASOPHARYNGEAL SWAB COLLECTION

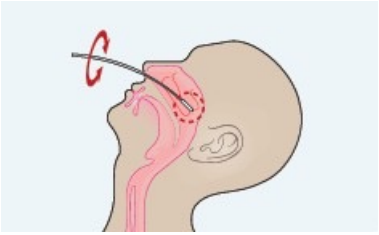
1. Remove a nasopharyngeal swab from package



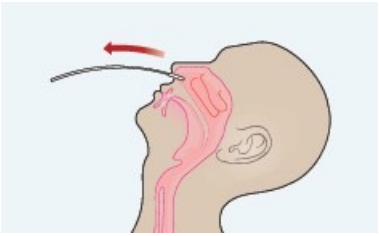
2. Insert the swab into one of the patient’s nostrils until it reaches the posterior nasopharynx.



3. Slowly rotate the swab around its 3–5 times over the surface of the posterior nasopharynx.



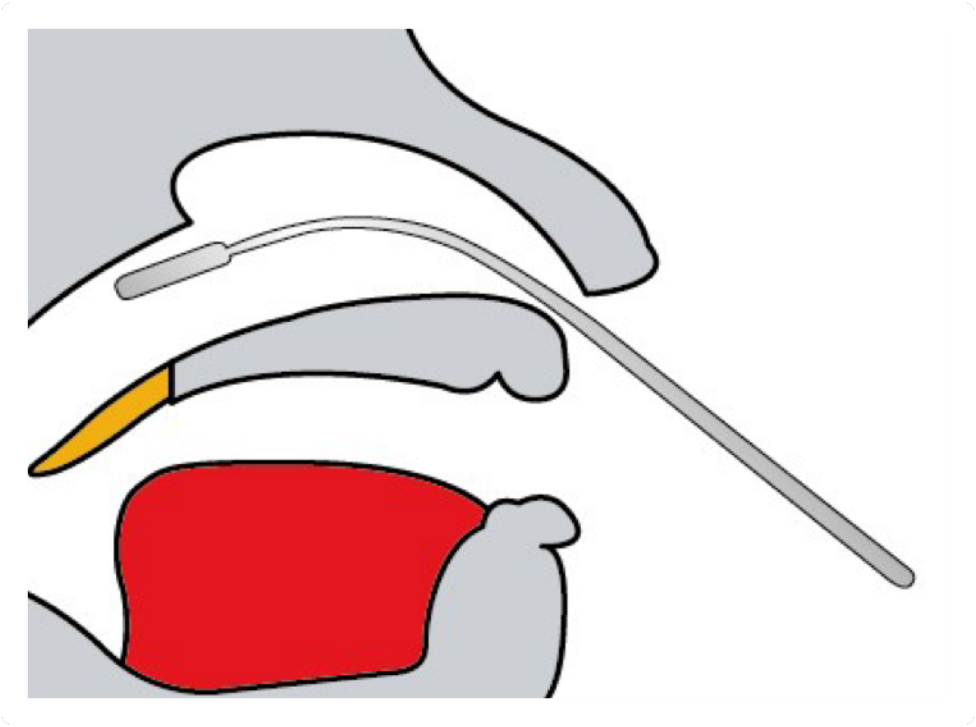
4. Remove the swab from the nostril.



IMPORTANT

The test should be performed immediately after sample collection. If this is not possible, the swab containing the sample can be stored for a maximum of 12 hours in the refrigerator, at a temperature between 2–8 °C, or for a maximum of 24 hours in a freezer at a temperature −20 °C.

NASOPHARYNGEAL SWAB COLLECTION



Gently insert a swab into the nasal cavity in order to collect a biological sample from the nasopharynx. Keep gently inserting the tampon until resistance is encountered in the nasal cavity.

Gently rotate the swab around its axis several times with your fingers and remove it from the nasal cavity. Visually verify that the tip of the swab is wet.

TEST PROCEDURE

Ensure that the biological sample and all kit components are at room temperature before performing the test.

Do not open an individual test cassette package until all preliminary manipulations are completed and test procedure is ready for immediate performance.

TEST STAGES

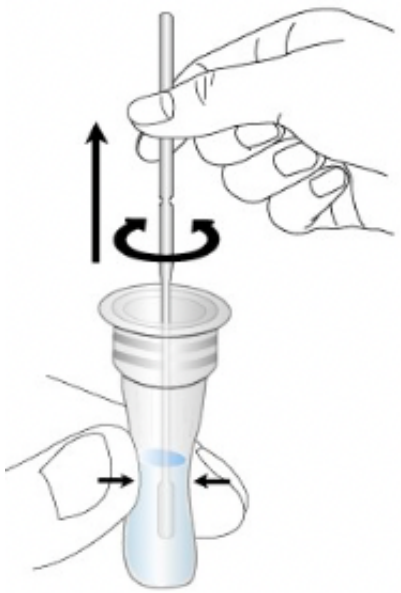
Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer. Place a swab with a smear from the nasopharynx area into the extraction vial with a buffer and press the swab tip against inner wall or bottom of the vial to release biological sample and transfer it to the buffer medium.

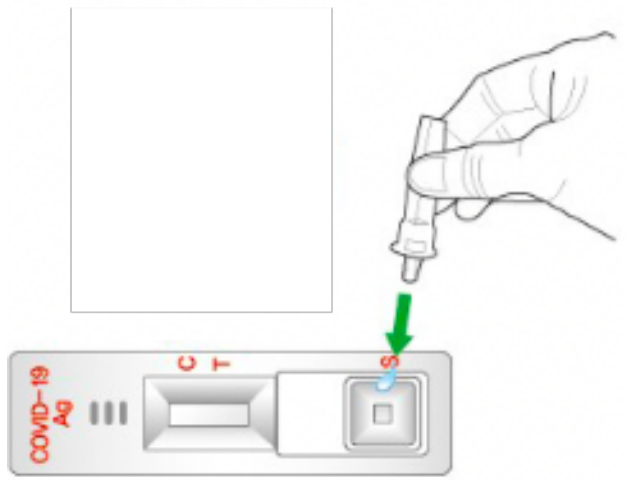
Keep on pressing the swab tip against the wall or bottom, make 5 to 10 circular movements.

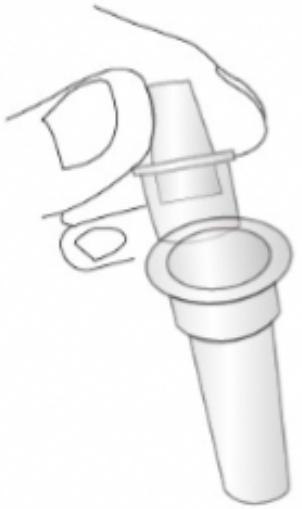
Press the tip of the swab against the inner wall to release the liquid, then remove the swab from the vial and dispose it in accordance with the hazardous biological waste disposal requirements.

Securely close the vial using the dropper cap from the kit.

Remove the test cassette from the individual package. Place the cassette on a dry, flat surface.





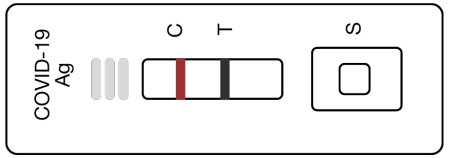


TESTING PROCEDURE SCHEME

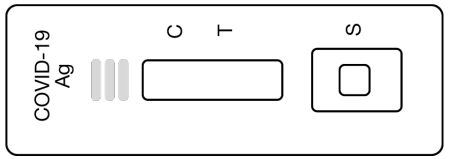
Read the test result in 10–15 minutes.

Note: strip width or color intensity are irrelevant.

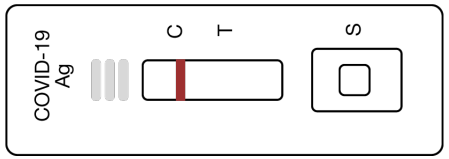
INTERPRETATION OF RESULTS



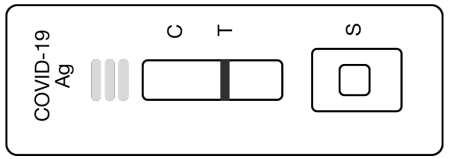
If only the control line (C) is colored red in the result window: the test is negative for the presence of the coronavirus antigen.



If the control line (C) is colored red and the test line (T) turns black in the result window: the test is positive for the presence of the coronavirus antigen.



If there is no red-colored control line (C) in the result window, the test result is considered invalid. The reason for such a result could be a violation of the biological sample collection and/or analysis procedures or the failure of the test cassette (test system) used.



LIMITATIONS

The test result can be negative if the coronavirus content (titer) in the biological sample is below the detection limit.

A negative test result does not rule out the presence of infection in cases of recent infection.

COMPETITORS

Coronavirus NowCheck COVID-19 Ag. rapid test, 1 pc.

Shelf life: long shelf life

BioNote, Inc., Korea

Price — RUB **1,850**

★★★★★ 13
Art. 502762

Buy

Coronavirus Standart Q COVID-19 Ag. rapid test, 1 pc.

Shelf life: long shelf life

SD Biosensor Inc., Korea

The product is out of stock
Last sale price

★★★★★ 34
Art. 502848

Send SMS
on arrival

Phone
RUB **3,000**

DUE TO THE HIGH DEMAND FOR SINGLE ANTIGEN TESTS AND LIMITED SUPPLY, THE MINIMUM RETAIL PRICE STARTS FROM RUB 1,850.