



autotest  
santé

## INSTRUCTION LEAFLET

- autotest COVID-VIRO® is a self-test to detect the virus causing COVID-19 in a nasal swab sample.
  - autotest COVID-VIRO® is a single-use device for in vitro diagnostics.
  - autotest COVID-VIRO® is intended for use by lay people in a private setting or accompanied by a healthcare professional.
  - It takes about 2 minutes to do the self-test and then a 15-minute wait to obtain the result reading.
- Make sure you have a timer.**
- Read the instruction leaflet carefully and in full before starting the test.

autotest COVID-VIRO®  
comes in 3 presentations:

- AS-COV-002 = 1 test in the box
- AS-COV-003 = 3 tests in the box
- AS-COV-004 = 5 tests in the box

### CONTENTS OF THE BOX 1 TEST



Sachet **A**



Cassette **B**

Desiccant  
(to be discarded)

**C**



Tube containing  
a diluent **D**



Dropper  
cap **E**



Nasal  
swab **F**

AAZACV16 (20210906) Instruction leaflet autotest COVID-VIRO®

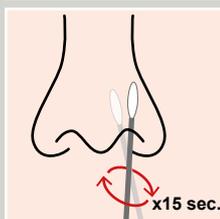
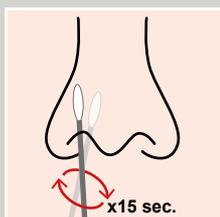
## STEP 1

1. Allow the self-test to reach room temperature (15–30°C), then wash and dry your hands.
2. Insert diluent tube **D** into the pre-cut hole in the box and then open the tube by removing the seal.



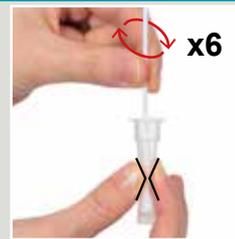
## STEP 2

1. Insert swab **F** into one nostril.  
The tip of the swab must be inserted 2 to 4 cm inside the nostril until resistance is felt.  
  
Rotate it at least 5 times (for 15 seconds), rubbing the swab against the inside of the nostril.
2. Repeat the procedure in the other nostril with the same swab **F**.



## STEP 3

1. Submerge the swab in the diluent in tube **D** and turn it at least 6 times, while pressing the end of the swab against the bottom and sides of the tube.



2. Leave the swab in diluent tube **D** for 1 minute.



3. Withdraw the swab while pressing it against the walls of diluent tube **D**, and discard it.



4. Insert dropper cap **E** into diluent tube **D**.

**PRESS FIRMLY; THE DROPPER CAP MUST BE FULLY INSIDE THE DILUENT TUBE.**



## STEP 4

1. Remove cassette **B** from sachet **A** and place it on a flat surface.
2. Invert diluent tube **D** vertically, holding the dropper cap **E** above the small well (S) in the cassette.

Put 4 drops into the well (S) in the cassette, by squeezing the outside of diluent tube **D**.



## STEP 5

1. Make a note of the time and wait 15 minutes before reading the result.



**DO NOT LEAVE MORE THAN 20 MINUTES BEFORE READING**

**TO INTERPRET THE RESULTS, SEE OVER**

# INTERPRETING THE RESULTS

## NEGATIVE SELF-TEST

If your self-test resembles the picture opposite, your result is negative.

1 coloured line present: control line (C)

**YOUR SELF-TEST IS NEGATIVE**

You are probably not infected with the COVID-19 virus



## POSITIVE SELF-TEST

If your self-test resembles the picture opposite, your result is positive.

2 coloured lines present: control line (C) and test line (T)

**YOUR SELF-TEST IS POSITIVE**

You are probably infected with the COVID-19 virus

autotest COVID-VIRO® self-test is a reliable test; however:

- If you get symptoms that suggest COVID-19, do another test.
- If you have symptoms and are over 65 years of age, contact your doctor to discuss the need for additional examinations.

**1• You must take a confirmatory RT-PCR laboratory test.**

**2• You must self-isolate until you receive the result of your confirmatory test.**

**Contact a doctor if your symptoms become worse or you get unusual symptoms.**

DOWNLOAD THE APP



#Tous  
AntiCovid

For more information:  
<https://covid-19.sante.gouv.fr/tests>

**REGARDLESS OF YOUR TEST RESULT, YOU MUST CONTINUE TO FOLLOW PROTECTIVE AND DISTANCING MEASURES.**

If your self-test does not resemble either of the scenarios pictured, the result is invalid and your test did not work. You cannot draw any conclusions from it. You must do another test. If you get multiple invalid self-tests, please consult your doctor.

Once the test has been done, dispose of the cassette, the swab, the tube and its cap in accordance with local recommendations.

## SCOPE AND PERFORMANCE DATA

autotest COVID-VIRO® is an immunochromatographic test for qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in nasal samples.

**Reliability:** A comparative clinical study conducted at Orléans Regional Hospital showed a 99.5% correlation between results from the COVID-VIRO® self-test and those from the RT-PCR laboratory test.

**Sensitivity:** The sensitivity of this self-test has been estimated at 96.4% (with confidence intervals ranging from 82.3% to 99.4%), i.e. 3.6% false negatives\*.

**Specificity:** The specificity of this self-test has been estimated at 100% (with a confidence interval ranging from 97.8% to 100%). No false negatives were identified\*\*.

**Usability:** The usability study of this self-test by lay people showed that 99% of participants who use this self-test obtain an interpretable result and that 98% of self-tests are interpreted correctly.

**Interference:** Examination of samples containing substances likely to distort the results of this test and from people with conditions likely to do so revealed no notable interference.

\* False negative: a sample known to be positive for the target marker and wrongly classed as negative by the device.

\*\* False positive: a sample known to be negative for the target marker and wrongly classed as positive by the device.

## PRECAUTIONS AND WARNINGS

- autotest COVID-VIRO® is intended only for private use to detect the COVID-19 virus; under no circumstances should it be used for other diagnoses or other purposes.
- Store the self-test in its original package in a cool and dry place between 2°C and 30°C.
- If the box is stored in a refrigerator (between 2°C and 8°C), it must be brought to room temperature (between 15°C and 30°C) before use.
- The self-test is for single use only. Do not reuse it under any circumstances.
- Do not open the package until you are ready to do the test.
- Do not use the self-test after the expiry date.
- Do not use the cassette if the packaging is open or damaged.
- Do not do the test in a room where there is a strong current of air, such as from a fan or powerful air-conditioning.
- Storing the test in conditions other than those stated, or failing to comply with the limitations of use may produce inaccurate results.
- Despite the reliability of this test, there may still be false negative and false positive results. If you are in any doubt about the result of your self-test, contact your doctor.

- The self-test user should not make any medical decisions without consulting his/her doctor, whether the test is positive or negative.
- Do not mix the components of different batches of the COVID-VIRO® self-test.
- Do not use a swab other than the one supplied in the COVID-VIRO® self-test box.
- Leave the cassette on a flat surface until the result has been read.
- The test instructions must be followed strictly to obtain an accurate result.
- Do not use nasal sprays in the 12 hours before carrying out the test.
- The diluent contains a solution with a preservative. If the solution comes into contact with the skin or eyes, rinse thoroughly with water.
- AAZ-LMB accepts no liability arising from any use, distribution or dispensing of the COVID-VIRO® self-test or its parts that falls outside the indications and limitations of use stated in the current version of the instruction leaflet.
- To report a health-related adverse event: [https://signalement.social-sante.gouv.fr/psig\\_ihm\\_utilisateurs/index.html#/accueil](https://signalement.social-sante.gouv.fr/psig_ihm_utilisateurs/index.html#/accueil)

Additional information and a demonstration video are available at [www.autotest-sante.com](http://www.autotest-sante.com)

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Key to the symbols:

: Read the instructions carefully

: Do not reuse

: CE marking

: Expiry date

: Store between +2 and +30°C

: In vitro diagnostic medical device

[www.autotest-sante.com](http://www.autotest-sante.com)

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