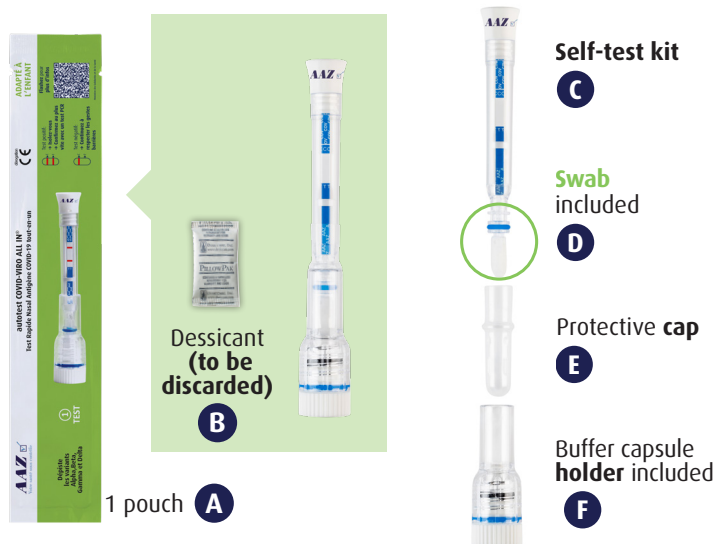**autotest COVID-VIRO ALL IN®**

# INSTRUCTION LEAFLET

— **autotest COVID-VIRO ALL IN®** is a self-test to detect the virus causing COVID-19 in a nasal swab sample.

— **autotest COVID-VIRO ALL IN®** is a single-use device for in vitro diagnostics.

— **autotest COVID-VIRO ALL IN®** is intended for use by lay people in a private setting or accompanied by a healthcare professional.

— The self-test takes approximately 1 minute. Wait 15 minutes before reading the results.

— Make sure you have a timer.

— Read the instruction leaflet carefully and in full before starting the test.

## SUITABLE FOR CHILDREN

### CONTENTS OF THE BOX 1 TEST :



Dessicant **(to be discarded)** **B**

1 pouch **A**

**Self-test kit** **C**

**Swab** included **D**

Protective **cap** **E**

Buffer capsule **holder** included **F**

**autotest COVID-VIRO ALL IN®** AS-COV-008 = **1 test in the box**
exists in 2 references : AS-COV-009 = **10 tests in the box**

AAZ-LMB
43, rue de Bellevue
92100 Boulogne-Billancourt - France

**Key to the symbols:**

📖 : Read the instructions carefully

CE : CE marking

🌡 : Store between +2 and + 30°C

② : Do not reuse

⌛ : Expiry date

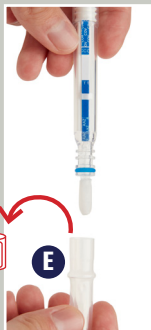IVD : In vitro diagnostic medical device

## STEP 1

Allow the self-test to reach room temperature (15-30°C), then wash and dry your hands.

Remove the self-test kit from the sealed pouch **A** just before use.

Blow your nose before doing the test.

**1.** Place the self-test kit on a table.
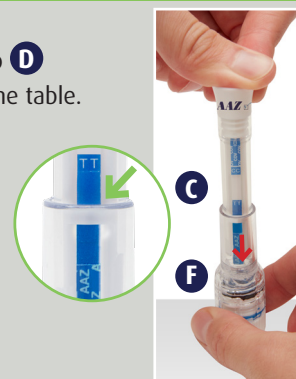Remove the self-test kit **C** from the holder **F** by pulling upwards.

**2.** Remove the protective cap **E** and discard it.

## STEP 2

**1.** Gently insert the swab **D** into your left nostril until you feel a slight resistance **(approximately 1 to 2 cm up your nose).**

Rotate the swab in your nostril **for 15 seconds** by wiping the sponge **D** against the inside of your nose.

**2.** Do this again for 15 seconds in your right nostril **for 15 seconds.**

15'' **D**

**D** 15''

## STEP 3

**1.** Put the self-test kit **C** with the swab **D** in it face down in the holder **F** on the table.

**a. Press down firmly** on the self-test kit to break the buffer capsule and push it to the bottom of the holder.

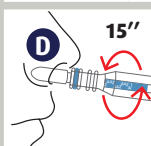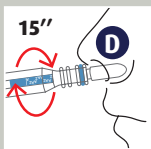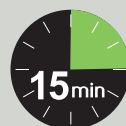**b.** Make sure a pink line appears within one minute.

If there is no pink line, **press very strongly** to push the self-test kit in completely.

**1**min

## STEP 4

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

**15**min

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

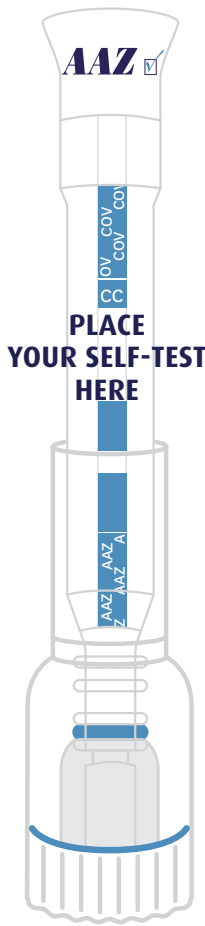**TO INTERPRET THE RESULTS, SEE OVER**

## 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**

PLACE YOUR SELF-TEST HERE

## POSITIVE SELF-TEST

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

2 colored 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 ALL IN® is a reliable test; however:
**1•** If you get symptoms that suggest COVID-19, do another test.
**2•** If you have any symptoms, contact your doctor to see whether further tests are required.

**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.**

---

**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 ALL IN® **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 97.5% correlation between results from the autotest COVID-VIRO ALL IN® and those from the RT-PCR laboratory test.

**Sensitivity:** The sensitivity of this self-test has been estimated at 93.02% (with confidence intervals ranging from 81,4% to 97,6%), i.e. 6,98% false negatives*.

**Specificity:** The specificity of this self-test has been estimated at 100% (with a confidence interval ranging from 95,2% to 100%). No false positives were identified**.

**Usability:** The usability study of this self-test by lay people showed that 98% of participants who use this self-test obtain an interpretable result and that 99% 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 ALL IN® 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 that 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 autotest COVID-VIRO ALL IN®.
• 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 autotest COVID-VIRO ALL IN® or its parts that falls outside the indications and limitations of use stated in the current version of the instruction leaflet.