



# INSTRUCTIONS FOR USE

**autotest VIH® 2<sup>nd</sup> GENERATION** is a screening test for HIV (the virus responsible for AIDS) based on a blood sample taken from the tip of the finger.

This self-test is **reliable for the detection of an HIV infection if the infection occurred at least 3 months ago.**

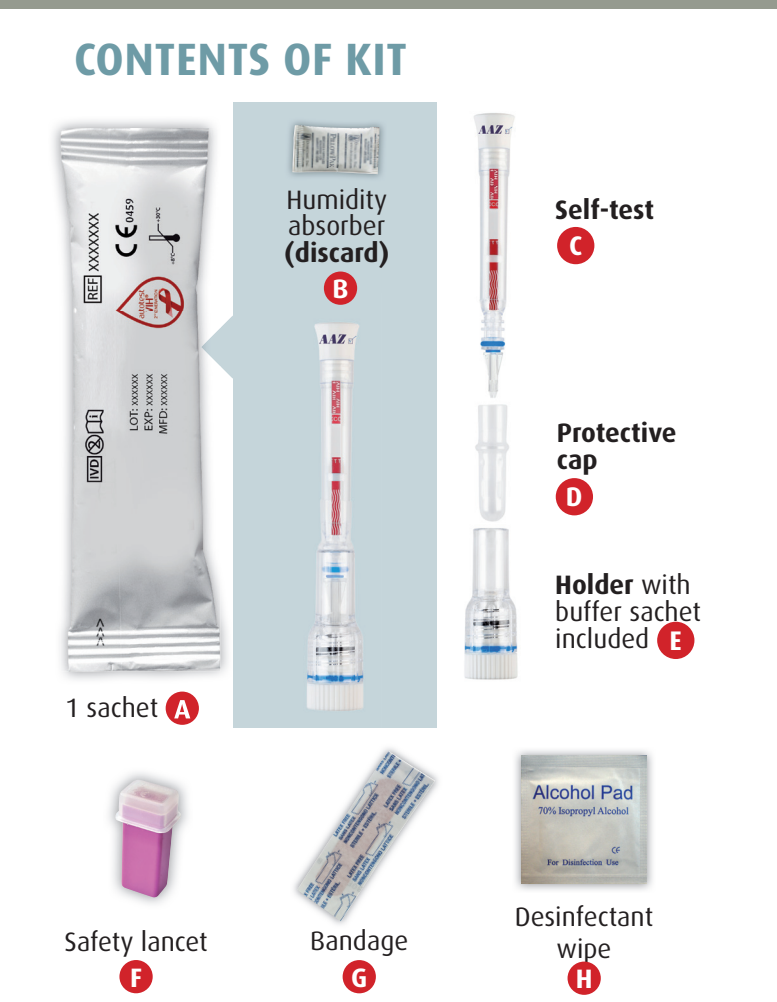
**autotest VIH® 2<sup>nd</sup> GENERATION** is a one-time use in vitro diagnostic test.

**autotest VIH® 2<sup>nd</sup> GENERATION** is intended for use by a layperson in a private setting.

The self-test takes about 5 minutes to perform and the wait time before reading the result is 15 minutes.

You will need a watch, clock, or other timing device.

Please carefully read all of the following instructions prior to using the test.



## STEP 1

1. Remove the self-test kit from the sealed sachet **A** immediately before carrying out the test.
2. Remove the self-test kit **C** from the holder **E** by pulling upwards.
3. Place stand **E** on the table.
4. Remove the protective cap **D** and discard it.

## STEP 2

1. Wash your hands, preferably with warm water and dry them.
2. Open the sachet containing the disinfectant wipe **H**.
3. Swab your fingertip with the disinfectant wipe and wait for the finger to dry.

## STEP 2 (CONTINUED)

4. Remove the transparent cap from the safety lancet **F**. Place the red end of the lancet onto the side your fingertip and press down firmly to prick your skin with the needle.
5. Gently squeeze your finger to form a first, large drop of blood.
6. Place the self-test **C** tip downwards in contact with the drop of blood as shown below until the white filter in the tip is completely soaked.

## STEP 3

1. **Immediately** insert the self-test **C** face down into the holder **E** on the table.
- a. Press firmly on the self-test to pierce the buffer sachet and push it to the bottom of the holder.
- b. Check that a pink line appears within one minute.

If a pink line does not appear, **press firmly once again** to fully insert the self-test kit.

## STEP 4

1. Check the time and wait for 15 minutes before reading the result.

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

**15min**

**INTERPRETING THE RESULTS - SEE OVERLEAF**

## STEP 5: READING THE SELF-TEST RESULT

### NON-REACTIVE SELF-TEST

If your self-test looks like the example below, the result is negative.

1 line appears: the control line.

This line may be light or dark.

**YOUR SELF-TEST IS  
NON-REACTIVE**

**YOU ARE  
PROBABLY  
HIV-NEGATIVE**

CONTROL →

PLACE YOUR  
SELF-TEST HERE

### REACTIVE SELF-TEST

If your self-test looks like one of the examples below, the result is positive.

2 lines appear: the control line and the test line.

Either of the lines may be lighter or darker than the other.

**YOUR SELF-TEST IS  
REACTIVE**

**YOU ARE  
PROBABLY  
HIV-POSITIVE**

← CONTROL TEST →



**autotest VIH® 2<sup>nd</sup> GENERATION** is a reliable test, however:

If your result is negative, it is important to ensure that you are not in the window period (seroconversion\*) and to consult a doctor.

If you think you may have been exposed to HIV in the last 3 months, you cannot be certain about being HIV-negative at this time. You will need to redo the self-test once 3 months have passed since your most recent risk of exposure to HIV.

\*Seroconversion refers to the period of time required for HIV antibodies to develop in sufficient quantity to become detectable.

**1. CONSULT A DOCTOR**, as soon as possible, and inform him/her that you have just done a self-test for HIV and that your result was positive.

**2. YOUR SELF-TEST RESULT MUST BE VERIFIED BY HAVING A CONFIRMATORY LAB TEST.**

**3. PROTECT YOURSELF and PROTECT OTHERS.**

**Avoid any activity that could transmit HIV to others until you have received the results of your confirmatory test.**

If your results do not look like the above examples, the result is invalid (no lines or just 1 line, the test line). This means that your test is not working. It is not possible to draw conclusions from this result and you will need to do another test. In the event of repeated invalid results, consult a doctor.



Used safety lancets might be classified as medical waste by health authorities in your area. To reduce the risk of injury from a used lancet, please follow local requirements for its disposal. Consult your pharmacist. For more information, see [www.autotest-sante.com](http://www.autotest-sante.com)

- > Are you in need of support?
- > Do you need help with the HIV home test?
- > Do you have questions about HIV or other STIs?



We're here for you.  
[www.hivpoint.fi/en](http://www.hivpoint.fi/en)

## PRINCIPLE AND PERFORMANCE

**autotest VIH® 2<sup>nd</sup> GENERATION** is an immunochromatographic assay that detects anti-gp41 and anti-gp36 antibodies in human blood produced following infection with HIV.

The presence of the control line is to verify the quality of the blood sampling and ensure that the test is working properly.

**Sensitivity:** the sensitivity of this test has been calculated to be 100% with a confidence interval of 99.2% to 100%.

All HIV-positive individuals in this study obtained a correct result. No false negatives\* were observed. However, false-negative results may occur.

**Specificity:** the specificity of this test has been calculated to be to 100% with a confidence interval of 99.8% to 100%.

All HIV-negative individuals in the study were correctly detected. No false positives\*\* were identified.

**Reliability:** a practicability study of the handling of this test by laypeople showed that 100% of participants obtained an interpretable result and over 99,88% correctly interpreted the result.

**Interference:** No significant interference was observed. Examination of samples with pathologies that could alter the results of this test showed limited cross-reactivity with samples positive for CMV IgM (1 in 15), EBV IgM (1 in 10), and malaria (1 in 10).

The summary of safety and performance (SSP) for autotest VIH® 2<sup>nd</sup> GENERATION is available on EUDAMED.

\*False negative: a specimen known to be positive for the target marker and mistakenly classified as negative by the test.

\*\*False positive: a specimen known to be negative for the target marker and mistakenly classified as positive by the test.

## WARNINGS AND PRECAUTIONS

- autotest VIH® 2<sup>nd</sup> GENERATION is strictly intended for private use as self-test for HIV and must not be used for any other diagnosis or purpose under any circumstance.
- autotest VIH® 2<sup>nd</sup> GENERATION must only be used with a fresh sample of capillary blood. Do not re-use for serum or plasma specimens.
- Store the self-test in its original packaging in a cool, dry location between 2°C and 30°C. Keep away from sunlight.
- autotest VIH® 2<sup>nd</sup> GENERATION is for single-use only. It should be performed between 18°C and 30°C. Do not re-use.
- Do not wait or store the test after the sampling step.
- The test must be inserted into its holder immediately after sample collection.
- Do not open the foil pouch containing the self-test device until you are ready to perform the test.
- This self-test is not intended for use in the context of therapeutic follow-up with patients receiving antiretroviral therapy.
- Individuals who use this self-test should consult their doctor prior to making any medical decisions, regardless of whether the test result is negative or positive.
- False positive results or false negative results could be obtained in the following circumstances: exposure to HIV in the 3 months prior to using the test (window period), situations of advanced immunodeficiency or infection by a rare variant, and among HIV-positive people receiving antiretroviral therapy.
- In Europe, the prevalence of HIV is 170 cases per 100,000 inhabitants.
- Strict compliance with the various testing steps, and in particular the volume of blood to be collected, is essential to obtain a correct result.
- Failure to store as directed or to respect the limits of use could cause the test result to be incorrect.
- Do not use the self-test if the packaging or foil pouch have been opened or damaged.
- Do not use if expiry date printed on the packaging has passed.
- If you have trouble understanding the package insert or instructions for use, **please contact Sida Info Service immediately at: [autotest-vih@sis-association.org](mailto:autotest-vih@sis-association.org) (7/7 - 8:00-23:00 GMT+1).**
- Keep this self-test and the items that come with it away from children, the components included with autotest VIH® 2<sup>nd</sup> GENERATION could be harmful if swallowed and could cause irritations.
- autotest VIH® 2<sup>nd</sup> GENERATION is an additional form of HIV testing that can be used as a complement to other existing options. autotest VIH® 2<sup>nd</sup> GENERATION is only able to detect HIV infection and cannot be used as a test for other sexually transmitted infections.
- Due to the potential risk of infection, once the self-test has been performed, dispose of all components in accordance with local recommendations.
- AAZ-LMB expressly disclaims all liability for the use or distribution of autotest VIH® 2<sup>nd</sup> GENERATION or any of its components, that fail to strictly follow the directions and limits of use as specified in the applicable Instructions for Use.

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

Manufactured by

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Legend of symbols:

carefully read  
Instructions for Use

do not reuse

IVD In vitro diagnostic  
medical device

expiry date

CE CE marking

Device for self-  
testing

store between  
+2°C and +30°C

Buffer Warning: contains Proclin (≥0.0015%), which  
may cause skin allergies.

FRENCH MANUFACTURER

AAZ.AV.49-E (20260610) Instructions for use of autotest VIH® 2<sup>nd</sup> GENERATION This document is available in a number of languages at [www.autotest-sante.com](http://www.autotest-sante.com)