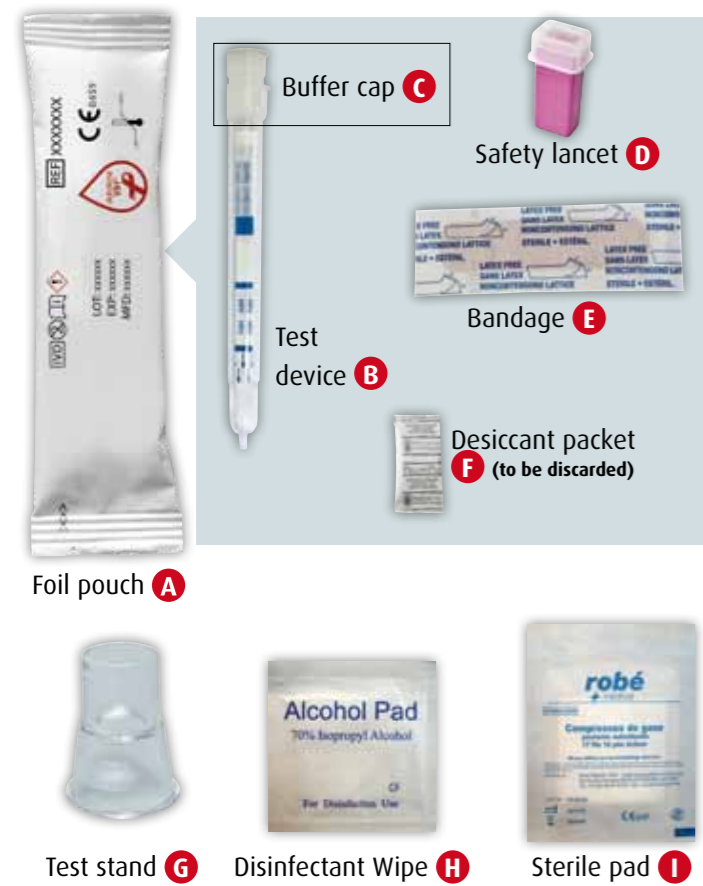




INSTRUCTIONS FOR USE

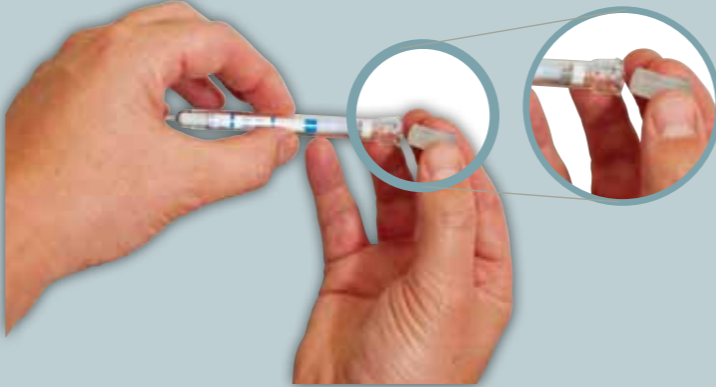
- autotest VIH® is a screening test for HIV (the virus responsible for AIDS) based on a blood sample taken from the tip of the finger.
- This self-test is **reliable for the detection of an HIV infection if the infection occurred at least 3 months ago.**
- autotest VIH® is a one-time use in vitro diagnostic test.
- autotest VIH® 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.

CONTENTS OF KIT

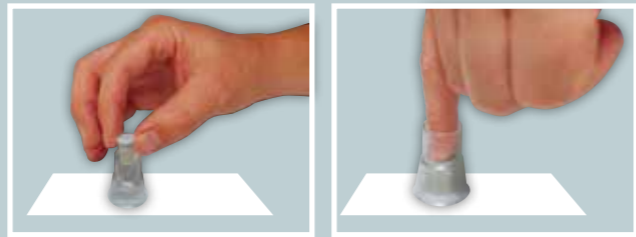


STEP 1

- Place the test stand **G** on a flat surface without vibration.
- Gently pull on the buffer cap **C** to separate it from the top of the testing device **B**.



- Drop it into the bottom of the test stand **G** using your finger.



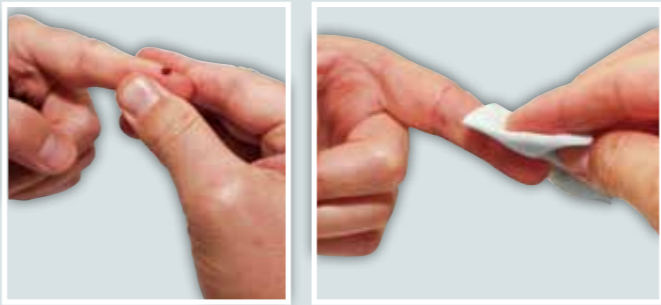
STEP 2 (STEPS 2 AND 3 MUST BE COMPLETED ONE RIGHT AFTER THE OTHER)

- Wash your hands, preferably with warm water and dry them.
- Open the packets containing the disinfectant wipe **H** and the sterile pad **I**.
- Swab your fingertip with the disinfectant wipe **H** and wait for the finger to dry.
- Remove the transparent cap from the safety lancet **D**. Place the red end of the lancet onto the side your fingertip and press down firmly to prick your skin with the needle.



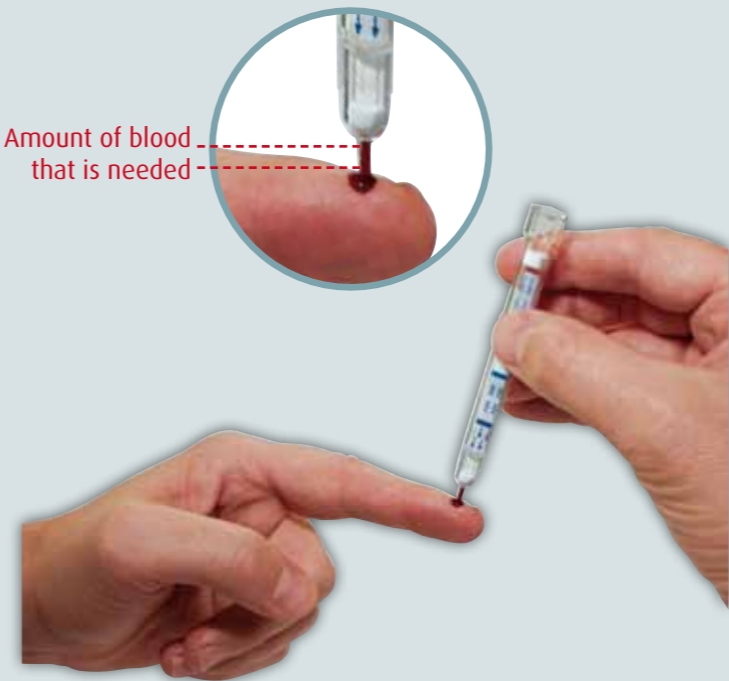
STEP 2 (CONTINUED)

- Gently squeeze your finger to form a first, large drop of blood. Wipe drop away using the sterile pad **I**.



- Without pressing too hard, gently squeeze your finger once again to form a new, large drop of blood.

- With the testing device **B** pointing downward as shown below (angle of 90°), touch the drop of blood with the tip of the device until the pointed end has filled with blood.



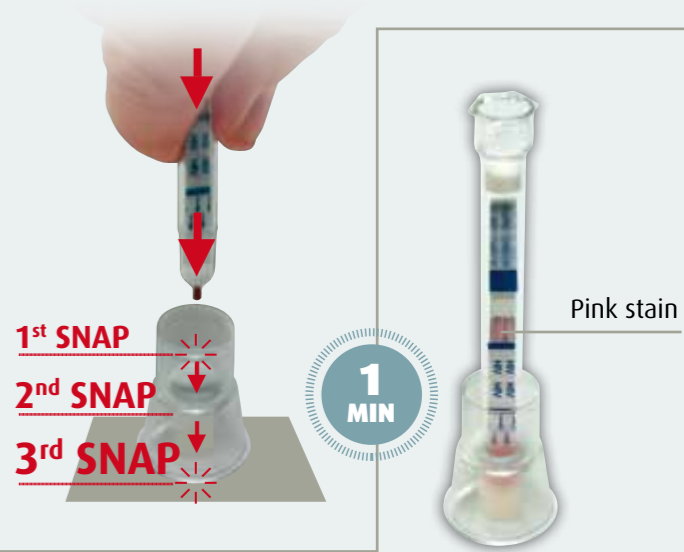
STEP 3

- Make sure the test stand **G** containing the buffer cap **C** is positioned on a flat surface without vibration.



- While holding the testing device **B** with the point downward, insert it firmly into the stand **G** to puncture the foil cover of the buffer cap **C**.

**PUSH DOWN VERY FIRMLY
YOU WILL FEEL IT SNAP THROUGH 3 TIMES**



- Check for a pink stain that will start to appear less than a minute after the test device and buffer cap have been snapped together.
- Apply the bandage **E** to your finger.

THE TEST IS IN PROGRESS

⚠ If the pink stain does not appear within one minute, push down more firmly on the test device **B** to insert it completely.

The test device must be kept upright until Step 4 has been completed.

STEP 4

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



Do not wait longer than 20 min to read the result



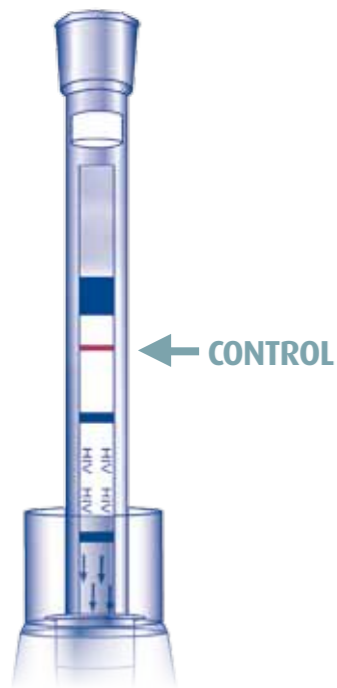
STEP 5: READING THE SELF-TEST RESULT

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

autotest VIH® 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.

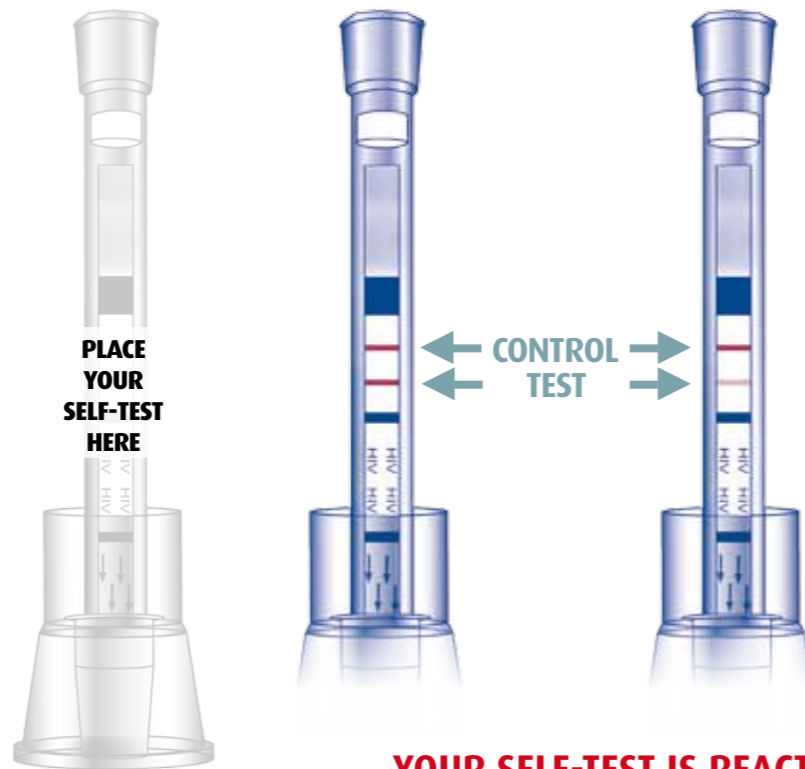
If your results do not look like the above examples, the result is invalid (no lines or just 1 line, the test line). This means that your test is not working. It is not possible to draw conclusions from this result and you will need to do another test. In the event of repeated invalid results, consult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

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

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.

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-vih.eu

- > Need support or guidance?
- > Need help with using the test or interpreting the result?
- > Questions related to HIV or other sexually transmitted infections?

7/7 8:00-23:00 GMT +1

Sida Info Service

autotest-vih@sis-association.org

PRINCIPLE AND PERFORMANCE

autotest VIH® is an immunochromatographic assay that detects antibodies in human blood that are produced following infection with HIV.

The control line that appears when the test is used serves to confirm that the test is functioning properly.

Sensitivity*: the sensitivity of this test has been calculated to be 100% with a confidence interval of 99.1% to 100%. All HIV-positive individuals in this study obtained a correct result. No false negatives were observed.**

Specificity*: the specificity of this test has been calculated to be to 99.8% with a confidence interval of 99.5 to 100%. 0.2% of HIV-negative individuals obtained an incorrect result, i.e. 0.2% of results were false positive.***

Reliability: a practicability study of the handling of this test by laypeople showed that over 99.2% of participants obtained an interpretable result and over 98.1% correctly interpreted the result. Postive results were interpreted correctly in 100% of cases.

Interference: no significant interference has been observed upon examination of specimens that contain substances or that present medical conditions with the potential to affect the results of this test.

Detailed information on results from the above-mentioned studies is available upon request at www.autotest-vih.eu

*Studies of 503 people (sensitivity) and 2051 people (specificity) from the United States and the European Union.

**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® 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® 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 8°C and 30°C. Keep away from sunlight.
- autotest VIH® is for single-use only. It should be performed between 18°C and 30°C. Do not re-use.
- 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 (0.2% in studies of test specificity) 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.
- 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 (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® could be harmful if swallowed and could cause irritations.
- autotest VIH® is an additional form of HIV testing that can be used as a complement to other existing options. autotest VIH® is only able to detect HIV infection and cannot be used as a test for other sexually transmitted infections.
- AAZ-LMB expressly disclaims all liability for the use or distribution of autotest VIH® 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-vih.eu

Manufactured by AAZ-LMB
Sogaris 217 - 94664 Rungis Cedex - France

Legend of symbols:

: carefully read Instructions for Use

: do not reuse

: CE marking

: store between +8°C and +30°C

0459

: In vitro diagnostic medical device

: expiry date

Buffer Cap Warning:
Contains sodium azide ≥ 0,2%; Harmful if ingested. Very toxic gas released upon contact with acid. Harmful to aquatic life, with long lasting adverse effects. Contains gentamicin sulfate. May produce an allergic reaction. Avoid all contact with eyes, skin and clothing. Remove spills.

Under license from CHEMBIO. AAZ.AV.49-A (20160919) Instructions for use autotest VIH® - This document is available in a number of languages at www.autotest-vih.eu

Self-test for the detection of HIV*

1 TEST

www.autotest-vih.eu

autotest VIH®

A screening test from a drop of blood

FRENCH MANUFACTURER

Easy to use

Results in 15 minutes

Contents:

- 1 foil pouch containing: 1 test device, 1 buffer cap, 1 safety lancet, 1 bandage
- 1 test stand
- 1 sterile pad
- 1 disinfectant wipe
- 1 package insert with instructions for use

www.autotest-vih.eu

IVD

Carefully read instructions for use

CE 0459

REF AS-VIH-011

LOT

AAZ.AV.48-A (20160919)

Self-test for the detection of HIV*

1 TEST

autotest VIH®

A screening test from a drop of blood

Easy to use

Results in 15 minutes

FRENCH MANUFACTURER

autotest VIH® is for single use only

PERFORMANCE

- 99.8% of uninfected individuals have been correctly detected
- 100% of infected individuals have been correctly detected

* HIV is the virus responsible for AIDS

For assistance in using the test or in interpreting the result, or for any other questions related to HIV, please contact:

Sida Info Service

autotest-vih@sfs-association.org