**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. The test is intended for use by a layperson in a private setting. The test takes about 5 minutes to perform and the wait time before reading the result is 15 minutes. Please carefully read all of the following instructions prior to using the test.

**CONTENTS OF KIT**

- Test stand G
- Buffer cap C
- Safety lancet D
- Desiccant packet F (to be discarded)
- Alcohol Pad
- Disinfectant Wipe H
- Sterile pad I
- Foil pouch A
- Bandage E
- Test device B

**STEP 1**

1. Place the test stand G on a flat surface.
2. Gently pull on the buffer cap C to separate it from the top of the testing device B.
3. Drop it into the bottom of the test stand G using your finger.

**STEP 2** (CONTINUED)

1. Make sure the test stand G containing the buffer cap C is positioned on a flat surface.
2. 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.
3. Check the time and wait for 15 minutes before reading the result.
4. Apply the bandage E to your finger.

**PUSh DOWN VERY FIrmLY YOU WILL FEEL IT SNap THrouGH 3 TIMeS**

1. Gently squeeze your finger to form a large drop of blood. Wipe drop away using the sterile pad I.
2. Without pressing too hard, gently squeeze your finger once again to form a new, large drop of blood.
3. 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**

1. 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.
2. 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.
3. 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.
4. 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.

**STEP 4**

1. Check the time and wait for 15 minutes before reading the result.
2. Do not wait longer than 20 min to read the result.

**Setting**

- To be disposed of immediately after use.
- Not to be used together with another test.
- The result of the test is not directly used for diagnosis, but only for personal use.
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.

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 TEST IS NON-REACTIVE

YOU ARE PROBABLY HIV-NEGATIVE

If your result is negative, it is important 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.

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

YOUR TEST IS REACTIVE

YOU ARE PROBABLY HIV-POSITIVE

autotest VIH® is a reliable test, however:

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

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.

Further information and a demonstration video are available at www.autotest-sante.com

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 the study obtained a correct result. No false negatives were observed.**

Specificity*: the specificity of this test has been calculated to be 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. Positive 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-sante.com

- *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 a 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 autotest VIH® is for single-use only. Do not reuse or re-use any 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.
- False positive: a specimen known to be negative for the target marker and mistakenly classified as positive by the test.
- False negative: a specimen known to be positive for the target marker and mistakenly classified as negative by the test.

Further information and a demonstration video are available at www.autotest-sante.com