**TEST HIV**
For self-testing

**EXACTO® TEST HIV** is a screening self-test for the detection of an infection by the HIV virus (HIV-1 or HIV-2), the virus responsible for AIDS (Acquired Immunodeficiency Syndrome).

The test contains antigens capable of detecting antibodies directed against the virus responsible for AIDS (HIV-1 or HIV-2). It must be used at least three months after the last risky exposure to give a reliable result.

**CONTENT OF THE KIT**
- Pouch A
- Dropper C
- Alcohol wipe E
- Lancet G
- Sterile pad F
- Transparent bag
- Flared bottle B
- Pouch D
- Pouch H
- Paper wipe
- Plastic cap

**Advice for Sampling**
First, wash your hands with hot water and dry them properly. Warming water helps improve blood circulation at the fingertips. You can let your hand loose along your body for around 1 minute in order for blood to flow in that area in larger quantities.

It is recommended to puncture the left hand for a right-handed person, and the right hand for a left-handed person. Please puncture preferably a side of the fingertips: it is where the blood flow is highest, and the sensitivity minimal. Avoid areas where the skin seems thicker, so more difficult to puncture. It is possible that a blood drop does not appear immediately. In that case, you may want a little bit and massage lightly the finger from its base to the punctured area. If the red square is not completely filled with blood (step 12), you can form a new drop of blood, collecting it with the same inverted cup, and then deposit this new drop in the square **BLOOD**.

Should you have any questions on how to run and interpret the test or want further information, please ask your pharmacist or local distributor or check the website: www.exacto.fr

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**TEST PROCEDURE**

**1.** Please read the instructions thoroughly. Have a watch or a timer (only equipment not provided).

**2.** Wash your hands with soap and hot water and then dry them before proceeding to the next step.

**3.** Take all the elements out of the box, place them on a flat and clean surface and identify each element of the kit (see content on the left, 7 elements to count).

**4.** Open the pouch A and pull the casette B out. Use the test within 1 hour.

**5.** Pull the alcohol wipe E out of its pouch; and disinfect the tip of the finger chosen for blood collection.

**6.** Take the sterile pad F out of its sachet; Wipe away traces of alcohol.

**7.** Take the lancet G on the fingertip. Trigger it by pressing firmly on the other end.

**8.** Apply the lancet G on the fingertip. Trigger A by pressing firmly on the other end.

**9.** Place the flared part of the inverted cup D on the drop of blood to fill entirely the cup.

**10.** Squeeze the tip of the finger to form a large drop of blood for the sampling.

**11.** Immediately deposit the drop of blood into the square well **BLOOD** of the casette B (the blood drop must be in direct contact with the bottom of the well).

**12.** Check that the bottom of the square well **BLOOD** is completely red before moving to the next step (this confirms that the drop of blood has been properly added).

**13.** Unscrew the cap of the dropper bottle C. Put two drops in the round well **DILUENT** of the casette B.

**14.** Start the timer or write down the time of deposit. Wait 10 minutes to read the result. Do not read beyond 20 minutes. During this time you can put on the plaster H.

**INTERPRETATION**

**NEGOATIVE**
If absence of Test band T and presence only of the Control band C (that indicates that the test was conducted properly).

- A NEGATIVE result can appear in a person who was infected over the last three months.
- You cannot conclude to be HIV-negative if you identify a risky exposure in the 3 months preceding this HIV screening self-test.

**POSITIVE**
If presence of Test band T (more or less intense), and presence of the Control band C, that indicates that the test was conducted correctly.

- A POSITIVE result must be confirmed by a laboratory test. To do so, please contact your doctor or go to a screening centre.
- Pending confirmation of your result, use condoms to protect yourself and others.

**HIV-NEGATIVE LIKELY**
If absence of Test band T and presence only of the Control band C (that indicates that the test was conducted properly).

- A NEGATIVE result can appear in a person who was infected over the last three months.
- You cannot conclude to be HIV-negative if you identify a risky exposure in the 3 months preceding this HIV screening self-test.

**HIV-POSITIVE LIKELY**
If presence of Test band T (more or less intense), and presence of the Control band C, that indicates that the test was conducted correctly.

- A POSITIVE result must be confirmed by a laboratory test. To do so, please contact your doctor or go to a screening centre.
- Pending confirmation of your result, use condoms to protect yourself and others.

**PERFORMANCE**
EXACTO® TEST HIV has undergone clinical assessments. A 99.9% correlation between EXACTO® TEST HIV and an ELISA laboratory test was observed.

A clinical study performed in hospitals using capillary blood showed that the EXACTO® TEST HIV has a sensitivity of 100% and a specificity of 100%.

A practicability study conducted with a laymen population showed that 97.8% of participants obtained a correct and interpretable result. A readability study confirmed that 98% of the different types of results were interpreted correctly.

EXACTO® TEST HIV can in rare clinical situations give erroneous results.

- HIV Self Test (general), a Finger-Stick Whole Blood HIV1/2 Exhibit a very high Sensitivity and Specificity in both HIV infected known patients and HIV negative individuals, 2016. CHR Orleans

A readability study confirmed that 98% of the different types of results were interpreted correctly.

**PRECAUTIONS FOR USE**
- Do not freeze. Keep in a dry place between 2°C and 30°C.
- Remove the test cassette from the sealed pouch and use it within 1 hour.
- Run the test in a place where the temperature is between 15°C and 30°C.
- The test must be run immediately after the capillary blood has been collected.
- Single use.
- The bottom of the square well **BLOOD** must be completely red before adding the diluent in the round well **DILUENT**.
- Keep the self-test and all components out of reach of children. Ingesting the diluent may be dangerous and the lancet could potentially cause an injury.
- The test is designed for the self-screening of users who are not aware of their serological status and must not be used for the following antiretroviral treatments (ART) of HIV-positive persons. People using ART may obtain false negative results when using EXACTO® TEST HIV. A medical follow up with regular testing is preconized in this case.
- Infected persons may get a negative result if they were infected less than 3 months before the test was conducted. If you think you experienced a risky exposure over the last 3 months, you must visit your General Practitioner (GP) to get a prescription for a 4th-generation ELISA test in a laboratory, or use this self-screening test at least 3 months after the last risky exposure. Over this 3-month period, use condoms to protect yourself and others.

- A positive result must absolutely be confirmed by a laboratory test. Consult your doctor.
- The diagnosis of an infection by the HIV virus can only be done by a doctor on the basis of biological tests run in a clinical laboratory. EXACTO® TEST HIV is merely an extra tool aimed at encouraging the screening of HIV infections.

**EXACTO® TEST HIV cannot detect other infections (sexually transmitted infections or others).**

Erroneous results can be obtained if:
- The instructions for use were not properly followed.
- The test was not conducted correctly (an expiration date indicated on the aluminum pouch)
- The test was not conducted immediately after the puncture was opened.
- Storage conditions were not respected or the test was conducted after the expiry date indicated on the aluminum pouch.

- Sufficient for use by patients who are not aware of their serological status and must not be used for the follow-up of HIV-positive persons.
- Single use.
- Run the test in a place where the temperature is between 15°C and 30°C.
- Do not freeze. Keep in a dry place between 2°C and 30°C.

* HIV Self Test (general), a Finger-Stick Whole Blood HIV1/2 Exhibit a very high Sensitivity and Specificity in both HIV infected known patients and HIV negative individuals, 2016. CHR Orleans

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**Give your feedback about EXACTO® Test VIH : www.exacto.fr**