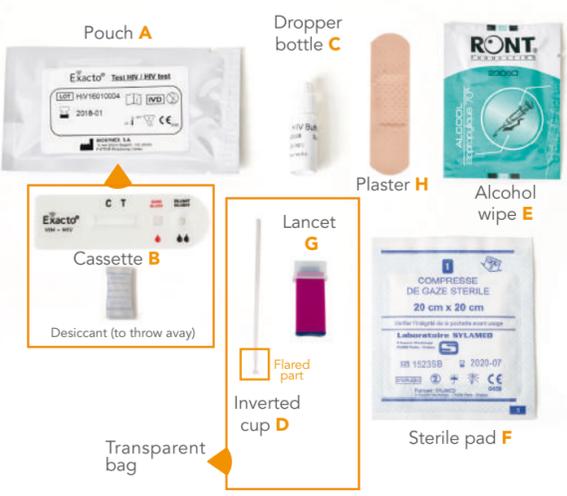


**TEST HIV**  
For self-testing



**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**



Ref 855164 contains one bag for one self-test.  
Ref 855169 contains two bags, one self-test can be run with each bag.

**ADVICE FOR SAMPLING**

First, wash your hands with hot water and dry them properly. Warm 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 fingertip: it is where the blood flow is higher, 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, please wait 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 on the virus responsible for AIDS, its modes of transmission of the virus or screening centres :

**WWW.SIDA-INFO-SERVICE.ORG**  
**SIDA INFO SERVICE : +33 (0) 800 840 840 (24/7)**

**BLOOD COLLECTION**

- 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 cassette **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** Remove the cap of the lancet **G**.
- 8** Apply the lancet **G** on the fingertip. Trigger it by pressing firmly on the other end.
- 9** Squeeze the tip of the finger to form a large drop of blood for the sampling.
- 10** Place the flared part of the inverted cup **D** on the drop of blood to fill entirely the cup.

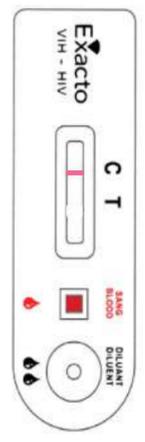
**TEST PROCEDURE**

- 11** Immediately deposit the drop of blood into the square well BLOOD of the cassette **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 cassette **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**

**NEGATIVE**

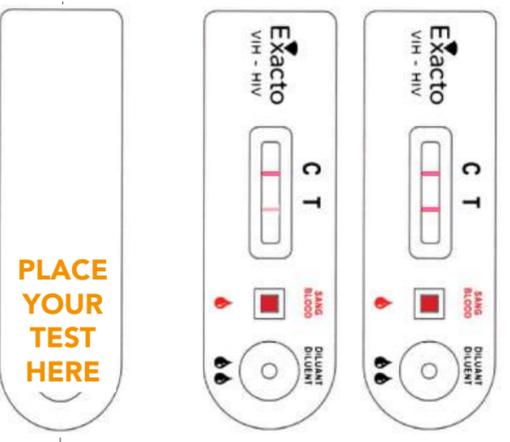


**HIV-NEGATIVE LIKELY**

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.

**POSITIVE**



**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.

- No band, or the test band T only : your EXACTO® TEST HIV is NOT VALID. Please do another test.
- To dispose of your test and its components, please check your local laws and current run regulations. For more information, please ask your pharmacist or local distributor or check the website : [www.exacto.fr](http://www.exacto.fr)

**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 Exacto®, 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 Orléans T.PRAZUCK et al.

**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 on hour.
  - Run the test in a place where the temperature is between 15°C and 30°C.
  - This 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.
  - This test is designed for the self-screening of users who are not aware of their serological status and must not be used for the follow-up of antiretroviral treatments (ART) of HIV-positive persons. People using PrEP may obtained 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 aluminum pouch was damaged or the test was not run immediately after the pouch was opened,
  - storage conditions were not respected or the test was conducted after the expiry date indicated on the aluminum pouch.

Consult instructions for use | IVD in vitro diagnostic medical device | Temperature limitation | DIL Diluant | Sufficient for Manufacturer | Do not reuse | Catalogue reference | REF 1 : 855164 | REF 2 : 855169 | Use by | LOT Batch code | Green point | TRIMAN unified signage | CE 0086