

**Important:**

- Thoroughly read the instructions for use before performing the test.
- This test is for single use. It is very important to familiarise yourself with all the instructions and make sure that you understand these instructions before using the test. Only perform the test as described. Failure to follow the instructions can lead to false or incorrect results.
- Store at room temperature (4 – 30°C) and keep out of reach of children
- Not for internal use. When producing the blood sample and carrying out the test avoid contact with your eyes or nose. Do not eat, drink or smoke near the test.
- Avoid others coming into contact with your blood, as it may be infected.
- Not for use by haemophiliacs or those taking medicines that thin blood (anticoagulants).
- The test should not be used after the expiry date (year and month, e.g. 2009 – 08) or if the package is damaged or opened. Return any damaged test to the place of purchase.
- As soon as you have used the test, place all used items back in the box and dispose as ordinary household waste.
- If symptoms persist irrespective of the outcome of the test, see your doctor.

**Contents of the kit:**

- 1 aluminium pouch containing a test device and a desiccating bag, which is supplied to keep the test device in good condition and is not needed for the use of the test.
- 1 lancet for the finger prick. The lancet can only be used once, so do not use the lancet until you are ready to do the test.
- 1 dropper bottle with test reagent
- 1 plaster



**Not included:**

- a clock or timer
- paper tissues

*Easy Home Test SYPHILIS Test – **What does it do?***

The Easy Home Test Syphilis Test is designed for *in vitro* detection of the antibodies produced against the bacteria that causes Syphilis. The test is simple to use. The results are available after just 10 minutes and you will know whether or not you have an infection.

*Easy Home Test SYPHILIS Test – **How does the test work?***

When someone is infected with the Syphilis bacteria their bodies produce antibodies against this. The Easy Home Test Syphilis Test can detect the presence of these antibodies in blood. One (no antibodies present) or two coloured lines (antibodies present) will appear in the oval reading chamber once the blood sample has been placed on the test strip. Consideration should also be given to the fact that it may take some time (days to weeks) after infection before the body is able to produce sufficient antibodies to be detected. A negative result may also occur after recent contact with the bacteria and this does not rule out an infection.

*SYPHILIS : background information.*

Syphilis is a bacterial STD (Sexually Transmitted Disease) caused by the bacteria *Treponema pallidum* (Tp). The bacteria nestle in the penis or vagina, the anus and sometimes even the mouth,

depending on the way of sexual intercourse. The bacteria may spread at a later phase throughout the entire body and can cause serious physical damage without rapid treatment. Syphilis is easily treatable, as long as the infection has been detected in time. There are various stages in a Syphilis infection. During the first stage one or more sores may occur around the penis, vagina, anus or sometimes mouth. This occurs two to twelve weeks after syphilis has been contracted. The sores will disappear within 2 to 3 weeks even without treatment. The second stage arises some weeks to months later. Syphilis has then spread through your blood stream throughout your entire body. Patches may occur on your skin and you may experience flu-like symptoms. These symptoms will also disappear by themselves. If the syphilis has not been treated in the first two stages, then the tertiary stage will follow. Syphilis is still present in your body and can cause serious damage to various internal organs.

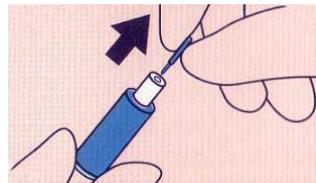
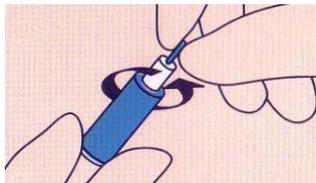
### **Test protocol – Procedure:**

- **Note: The test can give a false result if the protocol is not followed strictly.**

1). When you are ready to run the test, open the pouch that is marked as “Syphilis” and take the device out of the pouch. Place the device on a clean flat surface. Discard the little bag containing the desiccating material. Do not open the bag under any circumstances.

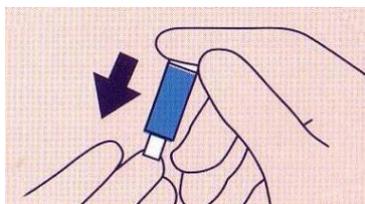
2). Before you do the finger prick, wash you hands with soap and water. Rinse them well and dry them thoroughly with a clean towel. Sit down and try to relax for about 5 minutes, whilst rubbing your hands together so that they are warm. Your finger should not feel cold and must be callus free.

3). Take the lancet, twist the coloured cap and pull it off.



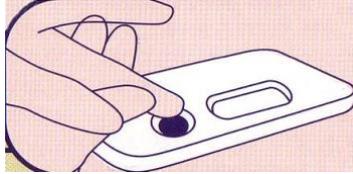
4). Place your hand, from which you are going to take the blood, flat on the table palm uppermost. If you are left handed, use the lancet on your middle or ring finger of the right hand. If you are right handed use the middle or ring finger of your left hand. Prick the side of your fingertip facing towards the little finger.

5). Place the lancet with the opening on the side of your finger as described earlier. Push the lancet down, at first it will travel easily downwards, then you will feel some more resistance. Continue to push until you hear a “click” and then you will feel the lancet pierce the skin. After the “click” you can remove the lancet from you finger.



6). Wipe away the first drop of blood with a clean paper tissue. Keep your arm down for about 10 seconds to stimulate the blood flow.

7). Keep your finger above the round sample chamber of the device and squeeze blood from the finger that you have pricked. Repeat this until a drop of blood is formed. Put the drop of blood in the chamber marked as sample. Make sure that the drop of blood touches the bottom of the chamber but not your finger. Do not smear the blood. Continue to add blood until the whole white circle is covered. The test is not affected by overloading the sample chamber with blood.



8). Add 6 drops of reagent from the dropper bottle to the sample chamber.

9). Wipe off the rest of the blood from your finger with a paper tissue and put the plaster on your finger.

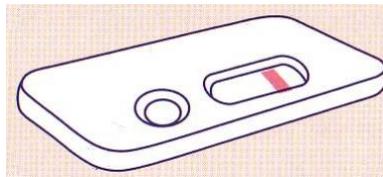
10). You can read the result after 10 minutes but within a maximum of 15 minutes.

### **Result of the test.**

During the 10 to 15 minutes whilst the test is working you will see one, two or no coloured lines appear in the oval reading chamber.

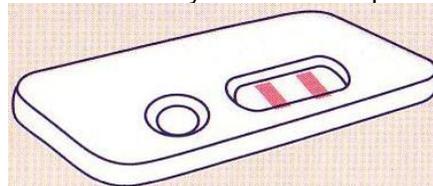
#### **Negative result:**

A single coloured stripe appears in the oval reading chamber. This means the test has been carried out properly, and that you are not infected with syphilis (see figure 1). However, it may also mean that the concentration of antibodies against the bacteria was too low in your blood sample to record a positive result. We would advise you to contact your general practitioner immediately if any symptoms persist.



#### **Positive result:**

Two coloured stripes appear in the oval reading chamber. Your blood sample contains the organism that causes syphilis (refer to figure 2). It is highly likely that you have been infected. Contact your general practitioner immediately as medical care is important for your recovery. There are however always exceptions which may cause a positive result, if you have not recently been infected with the bacteria. Usually the cause of this involves a related organism or a previous infection (treated). You should also contact your general practitioner immediately under these circumstances. The general practitioner should always order a new laboratory test and then prescribe the correct treatment.



#### **Undetermined result:**

There is no coloured line visible. The test has not been done correctly. Within 15 minutes you should see at least one coloured line in the reading chamber. Repeat the test after 2 days with a new test device and a fresh blood sample. Under no circumstances re-use the device with the undetermined result.

### **Additional Information**

- The Easy Home Test Syphilis Test should only be used on a blood sample for detecting antibodies of the organism which causes syphilis. The instructions should be followed properly. An erroneous result may arise if you do not follow the instructions properly.
- No diagnosis and/or conclusions should be made based on the results of this test alone. The diagnosis should be determined using laboratory tests, clinical examinations and your medical history. You should contact your general practitioner for this. Please consult a general practitioner if there are any doubts.
- An erroneous result may sometimes occur with patients who are serum positive for HIV.
- If you have questions, you can contact us on <country>@easyhometest.eu

### **Explanation of the used Symbols**

	Use by
	Batch code
	Date of manufacture
	Manufacturer
	In vitro diagnostic medical device
	Test Liquid
CE 0344	CE number (IVD)

IMHOTEP Medical Products  
 Jonckherenhof 7  
 6581 GC MALDEN  
 The Netherlands

Instructions version: 6 October 2008