RAPID TEST
FOR SYPHILIS
(SELF-TEST KIT)

GENERAL POINTS
Syphilis is a venereal disease that progresses through distinct stages of infection: primary, secondary, tertiary and quaternary. These stages produce diverse clinical symptoms, typically producing initial sores known as chancres then syphilitic rash followed by long periods of dormancy. Untreated infection eventually leads to cardiovascular problems and neurosyphilis. Caused by spirochaete Treponema pallidum (TP), the infection is usually acquired by sexual contact, although the disease may be transmitted by transfusion of infected blood. Intrauterine infection also occurs. The organism has proved virtually impossible to culture in artificial media, and diagnosis of the infection usually depends on the detection of antibodies in the blood, which appear soon after initial infection. Veneris Rapid Test for Syphilis is a highly specific immunological rapid test for the detection of anti-TP antibodies with a fingerprich whole blood sample.

PRESENTATION:
The box contains the material necessary to perform a test:
- 1 sealed aluminium pouch containing:
  1 test device, 1 desiccant pouch, 1 plastic dropper.
  Only open the protective pouch when you are ready to perform the test. The desiccant bag should not be used.
- 1 sample test tube containing 1 mL of diluent.
- 1 sterile lancet for blood sampling.
- 1 instruction manual.

PRECAUTIONS:
1. This test is exclusively intended to in vitro diagnostic. For external use only. Do not swallow.
2. Carefully read the instructions before performing the test. The test is only reliable if the instructions are carefully respected. Respect the indicated number of drops as well as reading time.
3. Keep stored between +4°C and +30°C. Do not freeze.
4. Do not use after the expiry date indicated on the label and the pouch. Do not use the test if the protective aluminium bag is damaged.
5. Do not reuse.
7. After use, all components can be discarded in a dustbin.

PROCEDURE

1. Wash your hands with soap and rinse with clear water.
2. Tear the protective pouch (from the notch) and only get out the device and the dropper. Dispose of the small desiccant pouch.
3. Clean the end of the forefinger or the middle finger with a cotton ball damped with alcohol.
4. Massage the end of the finger to enhance the blood flow.
5. As far as possible, avoid air bubbles. Place the lancet on the part of the finger which is cleaned with alcohol, in order to obtain a good contact. Press on the trigger button. The tip retracts automatically and safely after use. Massage the end that was stroking to stimulate the blood stop.
6. Without pressing the bulb, put in contact the plastic dropper with the drop. The fluid migrates into the dropper through capillarity to the line indicated on the dropper. You may massage again your finger to obtain more blood. If the line is not reached. As far as possible, avoid air bubbles. Push the entire orange small rod into the body of the lancet until hearing a click indicating the device is activated.
7. Put the blood collected with the dropper into the sample well of the device, tip pressing on the dropper bulb. Fill the sample well with a drop.
8. Read the result after 10 minutes. Do not interpret after 15 minutes.
9. If the result is positive, it means that anti-TP antibodies are present in blood and that you should consult a doctor to show the test results. Then, the doctor will decide whether additional investigation should be performed.
10. If the result is negative, it means that the test could not detect anti-TP antibodies in blood sample. Meanwhile it is recommended to consult a doctor if symptoms persist.

QUESTIONS AND ANSWERS

How does Veneris Rapid Test for Syphilis work?
When present in the body, TP induce the production of specific antibodies by the immune system. These circulating antibodies are able to recognize the spirochaete and to stick on them. Veneris test detects specifically these anti-TP antibodies in blood and therefore shows the spirochaete presence.

When can this test be used?
Veneris Rapid Test should be performed in case of appearance of clinical symptoms, the main ones being chancres and specific rash. The test can be performed at anytime of the day.

Can the results be incorrect?
The results are accurate as far as the instructions are carefully respected. Nevertheless, the result can be incorrect if Veneris Rapid Test for Syphilis gets wet before test performing or if the quantity of blood added to the sample well is not correct. The dropper provided in the box allows making sure the collected blood volume is correct. Very early stage of the infection could also lead to negative results due to the low concentration of anti-TP antibodies in blood.

How to interpret the test if the colour and the intensity of the lines are different?
The colour and intensity of the lines have no importance for result interpretation. The lines should only be homogeneous and clearly visible. The test should be considered as positive whatever the colour intensity of the test lines.

What is the line that appears under the mark C (Control) for?
When this line appears, it only means that the test was performing well.

If I read the result after 15 minutes, will the result be reliable?
No. The test should be read within 10 minutes after adding the diluent. The result is reliable up to 15 minutes.

What do I have to do if the result is negative?
If the result is positive, it means that anti-TP antibodies are present in blood and that you should consult a doctor to show the test results. Then, the doctor will decide whether additional investigation should be performed.

What do I have to do if the result is positive?
If the result is negative, it means that the test could not detect anti-TP antibodies in blood sample. Meanwhile it is recommended to consult a doctor if symptoms persist.

What is the accuracy of Veneris Rapid Test for Syphilis?
The Veneris Rapid Test for Syphilis is accurate and has been used for more than 15 years by professionals in the field. Although this test is reliable, false positive or false negative results can be obtained. Evaluation reports show an overall agreement of at least 97.8% with reference methods.

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