PHARMA *Southern Africa*

TETANOSTOP®
Ref. 92084/ZA

Self-diagnostic device for the assessment of tetanus protection in whole blood

GENERAL POINTS

Tetanus is a serious disease, leading to prolonged hospitalisation with sequelae which may lead to death (30% of cases). This infectious disease is due to the exotoxin produced by *Clostridium tetani*. This ubiquitous gram-positive anaerobic bacillus is occasionally present in animal digestive tracts, persists in animal droppings and in the ground in a very resisting sporulated form. In the case of wounding, it penetrates within the body. Then, the tetanus toxin blocks neurotransmitter release which leads to muscular contractions and spasms.

Since the disease confers no immunity, vaccination is the only prevention.

Immunoprotection is proven by measuring anti-tetanus antibody concentration.

The TETANOSTOP® test is a rapid immunodiagnostic test for the assessment of anti-tetanus antibodies from finger prick whole blood samples. In the case of negative results, a common vaccination against Tetanus is enough to re-build protection.

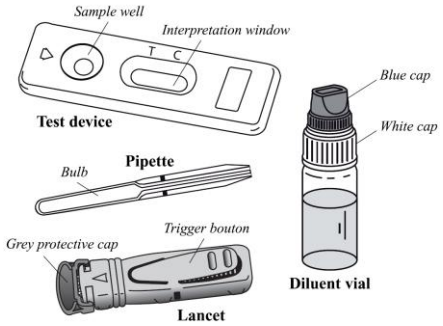
PRESENTATION

The box contains all the material necessary to perform a test:

- **1 sealed aluminium pouch containing :**
  1 test device, 1 plastic pipette and 1 desiccant pouch.

Only open the protective pouch when you are ready to use the test. The desiccant bag should not be used**.**

- **1 sterile lancet for blood sampling.**
- **1 dropper vial of 1 mL of diluent.** DIL
- **1 instruction manual.**
- **1 alcohol pad.**



Alcohol Pad

Material required but not provided: Timer

PRECAUTIONS

1. This test is exclusively intended for *in vitro* diagnostic use. For external use only. DO NOT SWALLOW.
2. **Carefully read the instructions before performing the test. The test can only be interpreted if the instructions are carefully respected. Follow strictly the indicated blood and diluent quantities, as well as the reading time.**
3. Store between +4°C and +30°C. Do not freeze the test.
4. Do not use after the expiry date printed on the label and on the protective pouch or if the pouch is damaged.
5. Do not reuse the TETANOSTOP® test.
6. **Keep out of the reach of children.**
7. After use, all the components can be discarded in a dustbin.

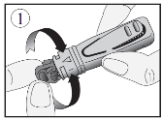
PROCEDURE

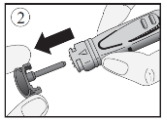
Testing procedure always starts with a good preparation. Place the content of the box on a clean, dry and flat surface (e.g. table). Then the testing follows:

1. Wash your hands thoroughly. Use soap and warm water. Dry your hand with clean towel.

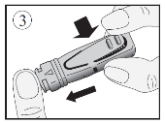
2. Prepare the test device and the pipette. Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant bag.

3. **Prepare the lancet.** Hold the lancet **without touching the trigger button.** Unlock the lancet cap twisting it off ¼ turn until you feel it separates from the lancet and then continue twisting it (2-3 rotations). **Don't pull just twist** and discard the cap when finished ① & ②.

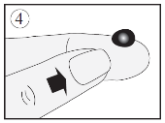




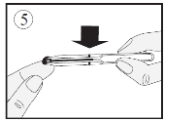
4. Clean the end of the middle finger or ring finger with the alcohol pad.
Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. **Press platform firmly against the lateral side of the previously cleaned finger and press the release trigger button**③.

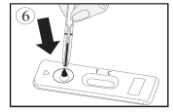


6. The tip will automatically retract into the body of the device.
7. Rub the finger's end to obtain enough whole blood sample.④.

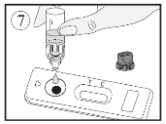


8. Without pressing the bulb, put in contact the plastic pipette with the blood sample⑤. The blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood if the line is not reached. As far as possible, avoid air bubbles.
9. Put the blood collected with the pipette into the sample well of the device, by pressing on the pipette bulb⑥





10. Wait 30-40 sec for the blood being totally absorbed into the sample well. **Unscrew the blue cap** of the diluent dropper vial (leave the white cap tightly screwed) and add the diluent as follows:
Hold the diluent dropper vial vertically and slowly add exactly 4 drops in the sample well of the device⑦ with an interval of 2-3 seconds between each drop.



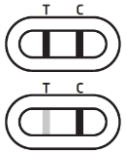
11. Read the result within 10 minutes. Do not interpret after 15 minutes.

RESULTS INTERPRETATION

The intensity and the colour of the lines do not have any importance for the interpretation of the test results.

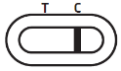
1. Positive result

Two coloured lines appear in the window under the marks T (Test) and C (Control). The intensity of the line T may be less than that of line C. This result means that there are enough anti-tetanus antibodies and therefore protection.



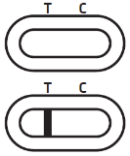
2. Negative result

Only one coloured line appears under the mark C (Control). **This result means that there are no (or not enough) anti-tetanus antibodies and there is no protection! You must absolutely consult your physician.**



3. Invalid result

No line appears or a coloured line appears under the mark T (Test) without any line under the mark C. In this case, it is not possible to interpret the test, which must be considered as invalid. It is recommended to repeat the test with a new TETANOSTOP® device and a new blood sample.



QUESTIONS AND ANSWERS

How does TETANOSTOP® work?
Protection from tetanus is assured when the antibodies, which have been generated by the immunological system by a previous vaccination, are present in the blood in sufficient quantities. The TETANOSTOP® test detects specifically the antibodies present when they are concentrated enough (>0.1 IU/mL determined against W.H.O.* reference).
World Health Organisation

When should the test be performed?
The test should be performed at any time of day. Generally immunological protection is effective for 10 years. The test can be used in normal conditions to check that the protection from a previous vaccination is still effective (i.e. a few years) or with the same aim but **in case of emergency** with a few hours of being wounded.

Can the results be incorrect?
The results are accurate as long as the instructions are carefully respected.
Nevertheless, the result can be incorrect if the TETANOSTOP® test gets wet before performing the test or if the quantity of blood dispensed in the sample well is not correct. The plastic pipette provided in the box makes sure that the collected blood volume is correct.

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 be homogeneous and complete. The test should be considered as positive regardless of the colour intensity of the test line (T), even weak.

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

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

What do I have to do if the result is positive?
If the result is positive, it means that the anti-tetanus toxin antibodies are present in a sufficient quantity to ensure protection in the case of wounding. It is recommended to perform the test regularly if the vaccination was done more than 5 years ago.

What do I have to do if the result is negative?
If the result is negative, it means that there is no protection against Tetanus and that it is absolutely necessary to be vaccinated or, in the case of wounding, have the post-exposure prophylaxis (immunoglobin) injection. It is recommended to consult your physician or your Emergency Service in the case of wounding.

What is the accuracy of TETANOSTOP® ?
The TETANOSTOP® test is accurate and is used by professionals in the field (hospitals, laboratories…). Evaluation reports show an overall agreement higher than 98.10% [92.62 - 100**] with reference methods. Although this test is reliable, false positive or false negative results could be obtained.
***CI 95%: 95% Confidence Interval.**

Information on Tetanos disease
https://www.who.int/fr/news-room/fact-sheets/detail/tetanus
https://www.doctissimo.fr/html/dossiers/tetanos.htm
https://www.mayoclinic.org/diseases-conditions/tetanus/symptoms-causes/syc-20351625

Sterile lancet: STERILE R — CE 1639

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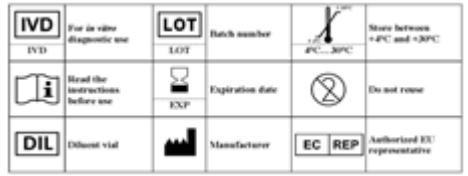

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CE 0483

CHANGES DESCRIPTION
Changes type :

- N/A	Not Applicable (creation)
- Technical change	Addition, revision and/or removal of information related to the product.
- Administrative	Implementation of non-technical changes noticeable to the end-user.

Changes type	Changes description
Administrative Change	Addition of alcohol pad in components and procedures

Note: Minor typographical, grammar, spelling and formatting changes are not reported in the change details.

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TETAMCOT601302