PHARMA *SOUTHERN AFRICA*

CRP-SCREEN®

Ref. 34084/ZA

PATENTED

Self-Diagnostic Test for the detection of C-Reactive Protein in blood.

GENERAL POINTS

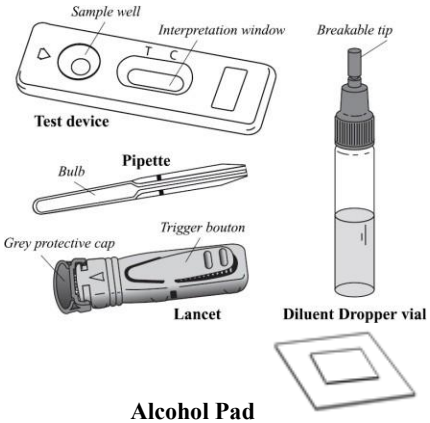
The C-Reactive Protein (CRP) is a non-specific marker which is mainly produced by the liver and used to diagnose bacterial infectious disease and inflammatory disorders.
The CRP is a very sensitive and fast appearing indicator which could therefore be helpful for deciding an antibiotic treatment.
Depending on the CRP concentration, different lines will appear allowing the semi-quantitative interpretation of the test result.
In healthy patients, CRP concentration is lower than 8mg/L while the concentration level can go higher than 100mg/L in case of severe infection or during inflammatory process. Intermediate levels, within 8 and 100mg/L, are concomitant with more or less mildly viral or bacterial infections that can be easily overcome by appropriate treatment ordered by your doctor.

PRESENTATION

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

- **1 sealed aluminium pouch containing:**
  1 test device, 1 plastic capillary 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 diluent dropper vial of 3 mL of diluent.** DIL
- **1 instruction manual.**
- **1 alcohol pad.**



Alcohol Pad

Material required but not provided: Timer

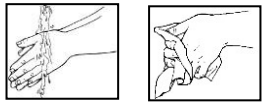
PRECAUTIONS

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

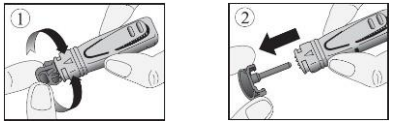
PROCEDURE

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:

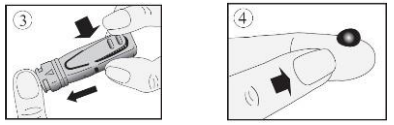
1. **Wash your hands thoroughly**. Use soap and warm water. Dry your hand with clean towel.



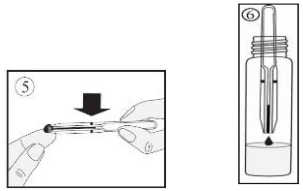
2. **Prepare the test device, the pipette and the diluent dropper vial.** Take them out from the protective pouch (tear at the notch) and place them in the reach of your hands (you will need them later). Discard the desiccant bag. Remove the screw cap of the diluent dropper vial and leave it nearby.
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.



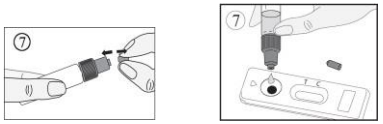
4. Clean the end of the middle finger or ring finger with the alcohol pad.
Rub the chosen finger towards the tip for 10 to 15 seconds to enhance the blood flow.
5. **Press platform firmly against the lateral side of the previously cleaned finger, and press the release trigger button**③.
6. The tip will 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 whole blood migrates into the pipette through capillarity **to the line indicated on the pipette**. You may rub again your finger to obtain more blood sample if the line is not reached. As far as possible, avoid air bubbles.
9. Place the collected whole blood sample into the previously opened diluent dropper vial by pressing the bulb of the pipette⑥. Make sure that the complete volume of whole blood sample is added into the diluent dropper vial by pressing 2-3 times the bulb of the pipette and therefore rinsing the inner part of the pipette with diluent solution. Replace the screw cap on the diluent dropper vial and mix thoroughly.



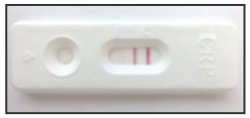
10. Break the tip of the dropper vial containing the diluted whole blood sample⑦. **Hold it vertically and slowly add exactly 4 drops in the sample well** of the device⑧ with an interval of 2-3 seconds between each drop.



11. Read the result after 5 minutes. Do not interpret after 10 minutes.

RESULT INTERPRETATION

The results must be interpreted depending on the intensity colour of the 3 lines that could appear in the device window.



1. CRP level lower than 8 mg/L: Only two lines (no line under the mark T (Test)) appear.

This result means that there is neither infection nor inflammation.

2. CRP level in the range of 8 to 40mg/L: Three coloured lines appear in the window but the intensity of the line under T mark is weaker than the intensity of the two other lines.
This result means that a viral infection could be on the way. **You should consult your doctor.**

3. CRP level in the range of 40 to 100mg/L Three coloured lines appear in the window and the intensity of the 3 lines are more or less equal.
This result means that a viral or bacterial infection is on the way. **You must consult your doctor.**

4. CRP level over 100mg/L
Three coloured lines appear in the window but the colour intensity of the lines under T and C marks are stronger than the colour intensity of the middle line.
In case of very high CRP concentration, the middle line may even disappear. This result means that a severe bacterial infection is on the way. **You must consult your doctor urgently.**

5. Non valid result
If no line appears under the mark C (Control), **it is not possible to interpret the test, which must be considered as non-valid** even a coloured line is visible under T (Test) mark and/or the middle line appears. In this case, it is recommended to repeat the test with a new CRP-SCREEN® device and a new blood sample.

QUESTIONS AND ANSWERS

How does CRP-SCREEN® work?
If present in the sample, CRP will interact with the anti CRP antibodies as well as with the CRP antigen placed in the test producing different lines allowing a semi-quantitative measurement of the CRP concentration de in the blood sample (< 8 to > 100mg/L determined against W.H.O.* reference). A control line capturing the reagent excess appears as a coloured line under the C mark of the cassette.
World Health Organisation.

When should the test be performed?
CRP-SCREEN® should be performed in the case of acute infection symptoms such as feverishness, fever, headaches or weakness. The test can be performed at any time of the day.

Can the result be incorrect?
The results are accurate as long as the instructions are carefully respected. Nevertheless, the result can be incorrect if CRP-SCREEN® gets wet before test performing or if the quantity of diluted blood dispensed in the sample well is not sufficient.
The plastic pipette provided in the box allows making sure the collected blood volume is correct and is correctly diluted into the diluent dropper vial.

How to interpret the test if the colour and the intensity of the lines are different?
The colour intensity of the lines is important to interpret the test result. So please refer to the pictures and instructions in paragraph "Result interpretation".

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 10 minutes, will the result be reliable?
No. The result should be read within 10 minutes. The result is reliable up to 10 minutes but should be better read at 5 minutes after adding the sample.

What do I have to do if the result is positive?
If the result is positive when the CRP is higher than 8mg/L, please refer to the result interpretation and inform your doctor as soon as possible as an antibiotic treatment might be urgently needed.

What do I have to do if the result is negative?
If the result is negative when the CRP is lower than 8mg/L, it means that there is neither bacterial nor viral infection on the way. However, if the symptoms persist, it is recommended to consult your doctor.

What is the accuracy of CRP-SCREEN®?
The CRP-SCREEN® is accurate and is used for more than 10 years by professionals in the field (hospitals, laboratories…). Evaluation reports show an overall agreement higher than 98.94% [93.85 - 100**] with reference methods. Although this test is reliable, false positive or false negative results can be obtained.
***** CI 95%: 95% Confidence Interval.***

Information on C Reactive Protein
https://www.passeportsante.net/fr/Actualites/Dossiers/DossierComplexe.aspx?doc=c-reactive-proteine
https://www.mayoclinic.org/tests-procedures/c-reactive-protein-test/about/pac-20385228
https://www.mayocliniclabs.com/test-catalog/Clinical+and+Interpretive/9731

Sterile lancet: STERILE R CE 1639

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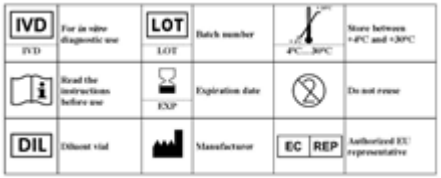
Owen Mumford GmbH, Alte Häge 1, 63762 Großostheim, Germany



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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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CRP-MCOT601002