DyonMed S.A.
Point of Care Solutions

182-184 Lavriou Av., 15354, Peania, Attika
Tel. (+30) 210.66.55.494 & -495, Fax: (+30) 211.770.8599
info@dyonmedical.com — www.dyonmedical.com
ISO 9001:2008 (No. 010110003)| ISO 13485:2003 (No 01210005)
by TÜV Austria Hellas

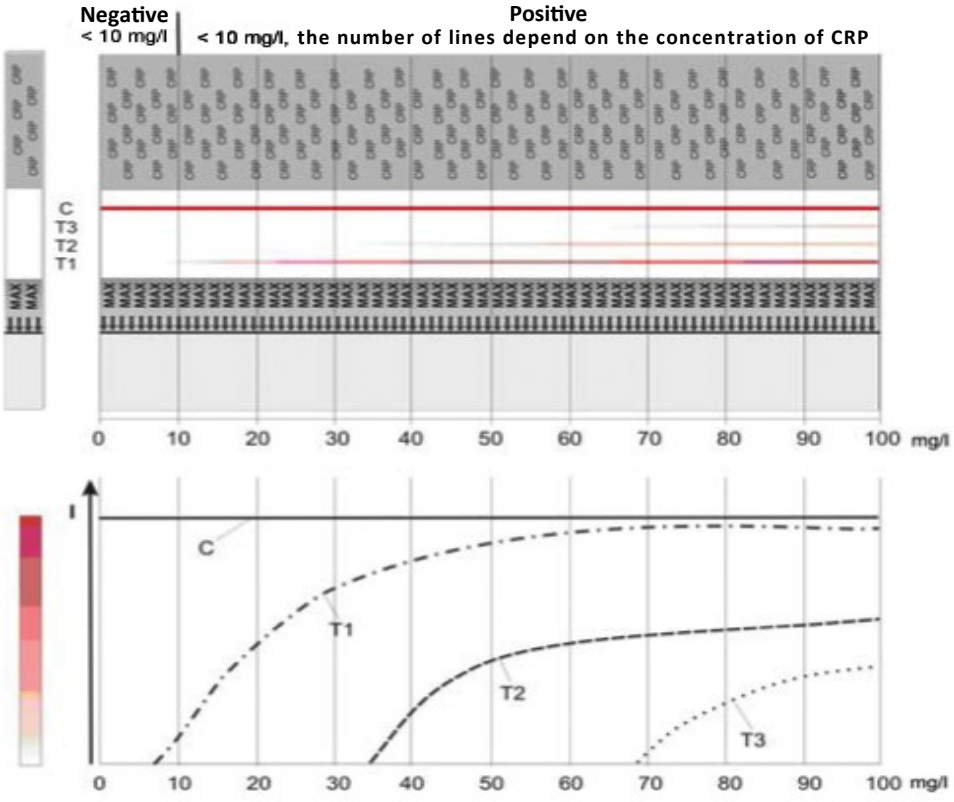
DyonCRP® (C-reactive protein)

Semi-quantitative detection of C-reactive protein of whole blood, fingerstick blood, serum or plasma

INSTRUCTIONS OF PROCEDURE

TEST PROCEDURE-INTERPRETATION OF RESULTS

Prior to testing, ensure that the final sample and the plastic package with test cassette have come to room temperature. The test cassette must be opened only shortly before the examination, since the method is sensitive to moisture.
Open the foil pouch and remove the test strip at the end of which is printed the word «CRP». Avoid diligently to touch the white response area.
Open the tube with the diluted specimen (step 7) and dip the test strip into the liquid backwards. Make sure that the test region immersed only to the point "MAX". Avoid splash reaction area with wet or immerse it deep into liquid.
Allow the test strip in the sample for about 15 seconds or until a pink liquid forehead appears to move in reaction area.
Remove the test strip and place it on a flat, non-absorbent surface. Alternatively, the test strip can be left in the vial. Start the timer.
Wait for colored lines. Interpret the result just after 5 minutes. (Interpretation of the test results for a time longer than 5 minutes will give values greater than the actual)



Positive Results = at least two colored lines.
The test result is positive **Dyon**CRP® for CRP where the control line (C) and at least one of the lines T1, T2 and T3 are simultaneously visible. The appearance of the effect of the test lines (T1, T2 and T3) depends on the concentration of CRP in the sample. The higher the concentration of CRP in the sample the more lines are visible, as follows:

- When the red line the result of the examination (T1) and the red control line (C) are also visible (albeit to varying degrees): the sample contains at least 10 mg / l CRP. The greater the concentration of CRP, the more enhanced will be the color intensity of T1.
- When redrawn result of the examination (T1) and (T2) and the red control line (C) is also visible (albeit to varying degrees): the sample contains at least 40 mg / l CRP. In these conditions, the color intensity of T1 is greater than that of T2.
- When all the red lines result of the consideration T1, T2 and T3 and the red control line (C) is also visible (albeit to varying degrees): the sample contains at least 80 mg / l CRP. Accordingly, the colour intensity of T2 is greater than that of T3.

The formation of the test line, which depends on the concentration of CRP, illustrated in the diagram below. Note that the number of lines of test results increases with increasing concentration of CRP. The colour intensity of the lines is weak in appearance, but later increased with increasing concentrations of CRP.
Note that the three lines have different colour intensity. For the range of concentrations shown in the diagram the colour intensity of the lowest line is the strongest, and the middle, and especially the upper line of the test results have clearly lighter colour intensity of the lowest line.
The colour of the control line is independent of the concentration of CRP or that of linear results of the test presenting always bright red colour.

STORAGE AND SHELF LIFE

Store the kit at 2-30 ° C. If the kit was stored in the refrigerator, it should be transferred to room temperature before proceeding with the examination. Under these conditions, the kit is stable until the expiration date printed on the package .

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INSTRUCTIONS OF SAMPLE COLLECTION

PRINCIPLE OF THE METHOD

The test strip **DyonCRP®** with the tip immersed in the sample , which is diluted in buffer. The sample migrates along the test strip from the bottom to the tip thereof. If the sample contains CRP, it bounds to the first antibody anti -CRP, which is connected to red labelled colloidal gold. The red labelled CRP- antibody complex now migrates with the sample along the membrane, wherein the second anti -CRP antibody is immobilized in lines of different concentrations. The labelled CRP-antibody complex is fixed by the immobilized antibodies of the membrane, resulting in the formation of red lines. The number of lines depends on the concentration of CRP in the sample. The more CRP is in the sample, the more red lines will appear. An additional red control line will appear at the end of the membrane, internal control review, stating the correct procedure. The formation of the control line is independent of the concentration of CRP in the sample. Failed to display the red control line means that the result is invalid. In this case the test should be repeated.

SAMPLING AND SAMPLE PREPARATION

1.Before use, make sure all the ingredients have come to room temperature. Cold buffer or any concentrated liquid in test strip can lead to invalid results.

2.Using a sterile tip, get a drop of blood (10 μl) from the tip of a finger.

3.Tap the supplied in the kit capillary tube in the punctured finger and observe the blood is transferred to a capillary until it reaches the maximum (about 10 μl) Dilute the collected blood directly (step 4) to avoid clotting.

4.Put the capillary, as is, with blood, in the tube of step 1 containing the dilution solution.

5.Close the lid and shake the tube vigorously for ~ 10 seconds, so that the blood is released from the capillary so that the sample and the diluting solution can be mixed completely.

6.Leave the diluted sample to stand in special racks for ~ 1 min.

7.The final sample obtained can be controlled directly or until after 8 h.

Note: the above steps are the same regardless of whether the presence of blood is taken EDTA, citrate or heparin.