Reactive Protein- C Agglutination Assay for glass slides
No prior dilution of the sample.
For "in vitro" use only
Store at 2- 8 °C

INTRODUCTION
Reactive Protein- C (PCR) is an acute-phase protein present in the serum of healthy patients whose concentration can increase significantly with most bacterial and viral infectious episodes, damaged tissue, inflammation and malignant neoplasia. The concentration of this protein increases a few hours after the onset of a disease and can reach levels of 300 mg/l in 12 to 24 hours.

PROPOSED USE
This method is valid for determining PCR in human serum.

MATERIALS
Micropipettes: 50 μL and 100 μL.

FUNDAMENT OF THE METHOD
The method is based on the agglutination reaction of a suspension of polystyrene latex particles sensitized with highly purified antibodies to anti-reactive protein C. Agglutination is visible at a PCR serum concentration equal to or greater than 6 mg/l.

CONTENT
R1 Latex
Latex particles coated with goat IgG in a 50 mmol/l borate buffer solution.
   White Cap
Contains sodium azide 0.95 g/l Code: 1200301: 2.5 ml Code: 1200302: 5 ml
R2 Positive Control
PCR concentration: 40 mg/L. Human serum in glycine buffer solution
   Red Cap
150 mmol/l.
Contains sodium azide 0.95 g/L
R3 Negative Control
PCR concentration: 0 mg/l rabbit serum in glycine buffer solution
   Blue cap
150 mmol/L. Contains sodium azide 0.95 g/L

Glass slides for latex
Code 1200301: 8 x 6 slides Code 1200302: 16 x 6 slides
Applicator
Code 1200301: 1 pack x 25 Code 1200302: 2 packs x 25

CALIBRATION
The sensitivity of the latex reagent has been standardized against the International Protein Standard CRM 470 by BCR.

PREPARATION AND STABILITY
R1 is a suspension of latex particles. Homogenize before use by shaking gently
The droppers dispense a drop with a volume of approximately 50 μL, ideal for a good sensitivity.

The reagents should be stored at 2 - 8 C. Do not freeze. Under these conditions the components shall remain active until the date of expiry indicated on the label.

SAMPLE
Sera stored at 2 - 8 C remain active for 2 days. Do not use hemolyzed or contaminated sera. Do not use highly lipemic sera as this can cause non-specific agglutination. The samples containing fibrin residues should be centrifuged before the assay.

PROCEDURE  Qualitative method
1. Allow the reagents and samples to reach room temperature. Sensitivity of the assay drops with low temperatures.
2. Homogenize R1 Latex before use by shaking gently.
3. Check the reactivity of the reagent with positive and negative controls (see procedure described below.
4. Add 50 μl of the sample onto the circle on a glass slide. DO NOT DILUTE
(SEE Note. 1).

5.-Add a drop of R1-Latex next to the first drop.

6. - Mix both drops with an applicator and spread throughout the circle. Use a different applicator for each sample. Handle by the ends.

7. - Place the glass slide on a rotatory stirrer (80-100 RPM) and exactly after two minutes, observe the presence (or not) of agglutination. Do not wait too long as this can cause false positive results. If a rotatory stirrer is not available shake the preparation slowly in circular movements.
INTERPRETATION
-The presence of agglutination indicates a PCR level equal to or over 6 mg/L in the sample.
–The absence of agglutination indicates of level of PCR below 6 mg/L in the sample. In the semi-quantitative method, the titter is defined as the highest dilution with positive results.

Semi-quantitative method
1. Successive dilutions are made with 1/2 of the sample in saline solution (NaCl 9 g/l).
2. Proceed for each dilution as described in the quantitative test.

CALCULATION
The approximate concentration of PCR in the sample is obtained through the following formula:

\[ 6 \times n^\circ \text{dilution} = 6 \times 2 \times 6 \times 4 \times 6 \times 8 \times 6 \times 16 \text{mg/L} \]

REFERENCE VALUES
Up to 6 mg/l

FUNCTIONAL CHARACTERISTICS
-Detection limit: 6 mg/l
-Prozone value: negative up to 1600 mg/l.
-Diagnostic sensitivity > 95 %.
-Diagnostic specificity > 96 %.
-Interferences:
  Rheumatoid factor interferes starting at 100 IU/ml
  Bilirubin 342 μmol/l, Hemoglobin 10 g/l and Lipids 10 g: do not interfere.

PRECAUTIONS
The positive control is human serum. Although the presence of HB or anti-HIV antibodies has not been detected, this preparation should be handled with the same precaution as the trial serum, in other words, as potentially infectious. The reagents contain small amounts of sodium azide. Avoid contact with irritated skin and mucosa.

NOTES
1. Very high concentrations of PCR in the sample can give rise to false negative results. The sample should be re-assayed with a volume of 20 μl.
2. Clinical diagnosis should not be based on the results of only one assay. The clinical record of the patient should also be considered.

REFERENCE
1. Lars-Olof Hanson et al. «Current Opinion in infection diseases», 1997; 10: 196-201

PRESENTATION

<table>
<thead>
<tr>
<th>Cód.: 1200801</th>
<th>48 Determ.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cód.: 1200802</td>
<td>96 Determ.</td>
</tr>
</tbody>
</table>