

CRP D-test

CR 0100 CH

100 tests

SUMMARY OF TEST

C-reactive protein was first described in 1932 by Tillet and Francis who showed that the sera of patients suffering from acute infection precipitated with a non-proteic pneumococcus extract called C polysaccharide in the presence of calcium ions. The protein which caused this reaction was therefore called C-reactive protein. Later it was shown that C-reactive protein is frequently found in the sera of normal persons in very low concentrations, in most cases not exceeding a level of 6 mg/l.

However, during the inflammatory process, whether of an infectious or other nature, the titers of C-reactive protein can reach levels that are far above normal values. In these cases C-reactive protein titers increase and decrease more quickly than the red cells sedimentation rate. The increase of C-reactive protein occurs in a non specific way in different kinds of tissutar aggression, as for example in infectious states, rheumatic fever, rheumatoid arthritis, myocardic infarct, malignant tumor, abdominal abscess, peritonitis, burns, etc. For this reason a high C-reactive protein concentration in serum lacks diagnostic value when the patients illness is not defined. Nevertheless, it is very useful for following-up and monitoring such illnesses, as well as for the differential diagnosis in certain cases.

PRINCIPLE OF THE METHOD

Due to the presence of C-reactive protein in the serum, the latex suspension changes its uniform appearance and a clear agglutination becomes evident. This change occurs because the C-reactive protein present in the serum reacts with the IgG coated to the latex particles, starting the formation of a web between them.

KIT COMPONENTS

For in vitro diagnostic use only.

The components of the kit are stable until expiration date on the label.

Keep away from direct light sources.

Latex reagent: 1 x 5 ml (suspension) 100 tests

Composition: suspension of polystyrene latex particles coated with IgG anti-CRP, preservatives.

Store all components at 2-8°C.

MATERIALS REQUIRED BUT NOT SUPPLIED

Saline solution, agglutination slide, disposable stirring devices.

REAGENT PREPARATION

Use reagent ready to use.

Stability: up to expiration date on labels at 2-8°C.

Stability since first opening of vials: ≥ 60 days at 2-8°C.

Do not freeze.

PRECAUTIONS

Reagent may contain some non-reactive and preservative components. It is suggested to handle carefully it, avoiding contact with skin and swallow.

Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

SPECIMEN

Fresh serum.

Sample is stable 7 days at 2-8°C. Store at -20°C for prolonged periods. Bring at room temperature before analysis. Centrifuge samples if a turbidity appears.

QUALITATIVE TEST PROCEDURE

Allow the reagent to reach room temperature (20 to 30°C). Gently shake the reagent vial to disperse and suspend the latex particles in the buffer solution. Use the supplied pump dropper to mix well.

Place 0.050 ml of the serum on one section of the disposable slide.

Place a drop of reagent next to the drop of serum.

Mix both drops with a disposable stirrer covering the whole surface of the slide section.

Gently rotate the slide for 2 minutes manually or on a rotatory shaker (100 rpm).

Look for the presence or absence of agglutination after the aforementioned period of time under an artificial light source

INTERPRETATION OF THE RESULTS:

The presence of agglutination indicates a content of C-reactive protein in the serum equal to or greater than 6 mg/l.

The absence of agglutination indicates a negative result.

It is recommended to execute a semi-quantitative procedure on positive samples.

SEMI-QUANTITATIVE TEST PROCEDURE

Organize serial dilutions of serum, pipetting in six different areas of test slide 50 μ l of saline and 50 μ l of sample only in first area.

Always using the same pipette (loading and unloading several times) mix carefully content of first area, transferring 50 μ l in subsequent area and so on.

Discard 50 μ l from last (sixth) area.

Perform the test as described in previous qualitative section. The last evident agglutination will mark the sample approximate title.

Dilution	Approximate value of CRP (undiluted samples)
(1 : 2)	12 mg/l
(1 : 4)	24 mg/l
(1 : 8)	48 mg/l
(1 : 16)	96 mg/l
(1 : 32)	192 mg/l
(1 : 64)	384 mg/l

EXPECTED VALUES

Average value of C-reactive protein on 143 healthy subjects has been found to be 0.64 mg/l, with an interval from 0.08 mg/l to 3.11 mg/l (Clinical Chemistry 43:1; 52-58: 1997).

Each laboratory should establish appropriate reference intervals related to its population.

NOTICE

• Reaction times over 2 minutes could yield an overestimation of sample concentrations.

• As in any diagnostic procedure, if results appear to be incompatible with clinical picture, physician should evaluate data using this test together with other information.

QUALITY CONTROL

It is suggested to perform an internal quality control. For this purpose a suitable human based control sera has to be used.

Please contact Customer Care for further information.

TEST PERFORMANCE

Sensitivity

test will show positive results from a level of 6 mg/l.

Existence of prozone at high titer levels is unknown up to 1634 mg/l.

Specificity

a comparison between Chema and a commercially available product gave a specificity of 96.2% on 125 different samples.

Interferences

no interference was observed by the presence of:

hemoglobin ≤ 1000 mg/dl

bilirubin ≤ 20 mg/dl

lipids ≤ 1000 mg/dl

Rheumatoid factor (RF) could interfere if present at concentration ≥ 100 UI/ml.

Turbid or lipemic samples could give false positives.

WASTE DISPOSAL

This product is made to be used in professional laboratories. Please consult local regulations for a correct waste disposal.

S56: dispose of this material and its container at hazardous or special waste collection point.

S57: use appropriate container to avoid environmental contamination.

S61: avoid release in environment. Refer to special instructions/safety data sheets.

REFERENCES

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SYMBOLS

	for in vitro diagnostic use only
	lot of manufacturing
	code number
	storage at temperature interval
	expiration date (year/month)
	warning, read enclosed documents
	read the directions