C REACTIVE PROTEIN (CRP)

Qualitative and semiquantitative determination of C-reactive protein by agglutination to latex

TEST SUMMARY

C-reactive protein, contained in the serum, produces agglutination of latex particles coated with anti-CRP antibody.

SAMPLES

Fresh serum. Stability 7 days at 2-8°C. For longer periods of time it is recommended to freeze samples at –20°C. Frozen samples must be totally unfrozen and brought to room temperature before using. Samples in which turbidity is observed must be cleared by centrifugation before being analysed.

REAGENTS

Latex
Latex particles coated with anti-CRP antibody; conservative and stabilizer.

Positive control
Human base stabilized solution having a CRP concentration 30-50 mg/L.

Negative control
Protein solution not reactive with latex.

All reagents contain 0.095% of sodium azide.

REAGENTS PREPARATION AND STORAGE

Reagents are ready for the use.
The latex suspension must be resuspended with much care. When the suspension becomes homogeneous by sweet inversion, it is necessary to fill and to empty the dosage's pipette many times.
Stability: the components of this kit will remain stable until the expiration date stated on the label.
Store at 2-8°C. Do not freeze.

MATERIAL REQUIRED BUT NOT SUPPLIED

Physiologic solution.
COD. AK00110 Slide and disposable stirrers.

PRECAUTION

Reagent may contain not reactive and conservative components. It is opportune to avoid contacts with the skin and do not swallow.
Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.

QUALITATIVE PROCEDURE

Reagents	Samples	Positive Control	Negative Control
Sample	50 µl (1 gt)	--	--
Control +	--	50 µl (1 gt)	--
Control -	--	--	50 µl (1 gt)
Latex	50 µl (1 gt)	50 µl (1 gt)	50 µl (1 gt)

Mix using disposable stirrers and spreading homogeneously the mixture on the slide, then, shake slide for 2 minutes by a sweet rotating motion or by a stirrer at 100 r.p.m., and observe eventual agglutination using artificial light.

RESULTS INTERPRETATION

POSITIVE: A clear agglutination within 2 minutes.
NEGATIVE: No agglutination within 2 minutes.

In case of positivity it is opportune to titre semiquantitatively the serum.

SEMIQUANTITATIVE PROCEDURE

Prearrange serial dilution of the serum, pipetting in six slide areas, 50 µl of physiologic solution and 50 µl of sample in the first area. Using the same pipette (inspiring and discharging many times) mix carefully contents of first area and transfer 50 µl in the following area etc. Discharge 50 µl from last area. Dispense latex suspension, shake, and after 3 minutes observe agglutination. The titre is given by last clear agglutination. Procedure is in the scheme below .

Reagents	Area 1	Area 2	Area 3	Area 4	Area 5	Area 6
Physiologic	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Sample	50 µl	50 µl from 1	50 µl from 2	50 µl from 3	50 µl from 4	50 µl from 5
Reject 50 µl from last area						
Latex	50 µl	50 µl	50 µl	50 µl	50 µl	50 µl
Titre	12 mg/l	24 mg/l	48 mg/l	96 mg/l	192 mg/l	384 mg/l

EXPECTED VALUES

Generally CRP in healthy adults is below 5 mg/L, in a number of disease states these values often exceeded within 4 to 8 hours after an acute event and reach levels up to 500 mg/L. The average value of CRP on 143 healthy adults is resulted 0.64 mg/L with an interval from 0.08 mg/L to 3.11 mg/L. (Clinical chemistry 43:1; 52-58: 1997).
Every laboratory should be establish own reference intervals in relation to own population.

CLINICAL SIGNIFICANCE

C-reactive protein is a protein present in normal serum, which increases significantly after most forms of tissue injuries, bacterial and virus infections, inflammation, and malignant neoplasies. CRP contributes to non-specific defense by complement activation and accelerating phagocytosis. CRP testing has a high diagnostic value on a tentative diagnosis made on the basis of case history and clinical findings.

NOTE

- If reaction's times are bigger than 2 minutes, they may cause a over-estimation of samples concentrations.
- Human sera used in controls have been found negative in the reaction with HIV and HBsAg. However, they should be handled with care.
- If the results are incompatible with clinical presentation, they have to be evaluated within a total clinical study.

CALIBRATION

Positive and Negative control sera should be always used to distinguish an eventual background's agglutination of reactive.

TEST PERFORMANCE

Sensitivity
Test gives positive results as from concentrations of 6 mg/l (5-10 mg/l).
Not happened phenomenon of prozone in CRP concentrations studied until 1634 mg/dl.

Specificity
A comparison with an available commercial method gave following results on 125 samples compared, giving a specificity = 96.2%:

		LTA srl		
		+	-	TOT.
COMPETI TORS	+	44	2	46
		95.6%	4.35%	
	-	3	76	79
		3.8%	96.2%	
	TOT.	47	78	125

Interferences
Not happened interferences with:

Haemoglobin	≤ 1000 mg/dl
Bilirubin	≤ 20 mg/dl
Lipids	≤ 1000 mg/dl

Rheumatoid factor interfere to concentration ≥ 100 UI/ml.

Lipemic or turbid samples may give false positivity.

WASTE DISPOSAL

Product is intended for professional laboratories. Waste products must be handled as per relevant security cards and local regulations.

PACKAGING

CODE AK00110	**(100 TESTS)**
Latex	1 x 5 ml
CODE AK00111	**(100 TESTS)**
Latex	1 x 5 ml
Positive control	1 x 0.5 ml
Negative control	1 x 0.5 ml
Slide black spot	3
Stirrers	50
CODE AK00105	**(CRP Controls)**
Positive control	1 x 0.5 ml
Negative control	1 x 0.5 ml

REFERENCES

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MANUFACTURER

LTA s.r.l.
Via Milano 15/F
20060 Bussero (Milan) ITALY
Tel: ++39 02 95409034
Fax: ++39 02 95334185
e-mail: info@ltaonline.it
Website: http://www.ltaonline.it

SYMBOLS


Only for IVD use


Lot of manufacturing


Code number


Storage temperature interval


Expiration date


Warning, read enclosed documents


Read the directions


Biological risk

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